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LA JOLLA
PHARMACEUTICAL COMPANY

## WHAT IS LUPUS?

- A chronic, relapsing, debilitating, and ultimately fatal disease primarily affecting young women
- Morbidity and death in lupus
  - Renal disease is a leading cause, and up to 50% of lupus patients are affected
  - Infections due to treatment with immunosuppressive drugs are common and potentially life-threatening
- Other serious side effects of current therapy
  - Sterility, diabetes, hypertension, cancer
- Antibodies to double-stranded DNA are an important subgroup of antibodies that cause and exacerbate lupus renal disease.

## UNIQUE FEATURES OF RIQUENT

- Unlike other treatments for lupus, Riquent specifically targets and reduces antibodies to double-stranded DNA (dsDNA), which are believed to be the major cause of lupus kidney disease.
- Our clinical trials to date have shown that Riquent has an immediate onset of action.
   The drug rapidly removes many of the circulating antibodies to dsDNA from the bloodstream.
   Riquent is also designed to have a sustained effect on reducing the production of antibodies to dsDNA by directly suppressing or killing only the B cells that produce these antibodies.
- Riquent has been well tolerated in all 14 clinical trials, with no overall difference in the
  adverse event profiles for Riquent-treated patients compared with placebo-treated patients.
  This safety profile contrasts with current treatments that suppress the immune system and
  can lead to serious complications, such as life-threatening infections.
- Riquent is the only targeted therapy for lupus nephritis patients that is designed to delay or reduce the risk of renal flare and to improve proteinuria.

## RIQUENT'S COMMERCIAL POTENTIAL

- There are estimated to be between 500,000 and 1,000,000 lupus patients in the United States.
- There have been no new treatments for lupus approved in the last 40 years, and lupus-treating
  physicians predominantly rely on corticosteroids and older immunosuppressive agents that
  have serious side effects.
- · There is a large unmet medical need for lupus medications that are both efficacious and safe.
- If Riquent achieves positive clinical outcomes in the Phase 3 ASPEN study, it could provide a novel approach for lupus treatment.



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#### TO OUR STOCKHOLDERS:

In our report to you last year, we pledged to intensify our efforts to bring Riquent<sup>®</sup>, our novel drug candidate for treating lupus renal disease, nearer to approval. Riquent has the potential to be the first new and specific therapeutic approved in 40 years for the more than one million lupus sufferers worldwide.

We are pleased to report that our commitment to that purpose remains resolute and clear. Although much remains to be accomplished, we are heartened by the significant progress this year in our ongoing Phase 3 ASPEN (Abetimus Sodium in Patients with Lupus Nephritis) clinical trial, including positive interim antibody data, and we are optimistic that our goal is in sight.

### PROGRESS IN CURRENT PHASE 3 TRIAL

The Phase 3 ASPEN trial, which is designed to meet the needs of both the Approvable Letter and the Special Protocol Assessment we received from the U.S. Food and Drug Administration, is assessing the clinical benefit of weekly treatments with 300 mg or 900 mg of Riquent in patients with lupus nephritis. While treatment with the 100 mg per week dose is probably effective in some patients, based on the results of our previous Phase 3 trial, we believe that these higher doses will enable Riquent to reduce renal flares in significantly more patients.

In the past 18 months, we have made substantial progress with the Phase 3 ASPEN trial. We believe the ASPEN study will demonstrate the benefit of Riquent in reducing renal flares and proteinuria. We plan to complete the study as soon as possible, which requires us to achieve a pre-specified number of renal flares. With positive results, we plan to gain potential approval to market Riquent in the U.S., Europe, and other countries.

We have enrolled more than 600 patients in the ASPEN study and are currently targeting at least 740 patients. This is a very large study, the largest clinical trial conducted to date in lupus renal disease. To accelerate enrollment and address these challenges, we have increased our number of target clinical trial sites from 80 sites to about 145 sites worldwide. Enrollment requires extensive patient screening and evaluation to ensure that patients meet our specific trial criteria.

Very importantly, the higher doses used in this Phase 3 study are being well tolerated by our patients, and our independent Data Monitoring Board has completed three safety reviews of the study without identifying any safety concerns. To date, more than 350 patients in the trial have been treated with either the 300 mg or 900 mg dose of Riquent.

#### SUCCESSFUL FUNDRAISING

In April 2007, following our announcement of positive interim antibody-data analysis, we raised net proceeds of \$38 million in a follow-on public offering. These proceeds are being used primarily to continue funding the Phase 3 study. We intend to raise additional capital in fiscal 2008 to support our operations and continue the progress of our Phase 3 ASPEN study.

#### PREPARING FOR COMMERCIALIZATION

We are refining and developing our commercialization strategy. We have further strengthened our senior management team to ensure that we have the talent and expertise in place to meet future commercial challenges.

In May 2007, Niv E. Caviar, an experienced senior pharmaceutical executive, joined us as Executive Vice President, Chief Business Officer and Chief Financial Officer. Mr. Caviar had previously served as both Vice President of Business Development and then as Vice President and Head of Medical Dermatology Marketing at Allergan, a \$20 billion specialty pharmaceutical and medical device company. While there, he led deal formation activities across all business units and then all operational and strategic marketing functions to build Allergan's U.S. medical dermatology business. Mr. Caviar brings extensive commercial, business development, and strategic planning expertise to the company.

We are working to identify partners to commercialize Riquent outside the United States and to potentially work with us to commercialize Riquent within the U.S. Based on an assessment of the U.S. market, most lupus patients are treated by approximately 3,000 specialty Rheumatology and Nephrology physicians who we believe can be addressed by a small and focused commercial organization. To help plan for future commercial efforts, we are involving lupus opinion leaders and patient advocacy groups in our pre-launch preparation activities to ensure that Riquent is positioned to best meet the needs of the lupus market.

We presented Riquent data at four important medical conferences this year: the 8th International Lupus Congress in Shanghai; the Biomarkers and New Therapies in SLE Conference in London; and the annual meetings of the American Society of Nephrology and the American College of Rheumatology. At all four conferences, we met with lupus medical experts to discuss Riquent clinical data and obtain their guidance.

We are exploring the possible benefits of Riquent beyond the potential to reduce the risk of renal flare. We believe the Phase 3 ASPEN study will also demonstrate the clinical benefit of Riquent treatment to reduce proteinuria. Furthermore, Riquent's ability to reduce antibodies to double-stranded DNA may have a broader impact, such as a general clinical benefit in lupus and the potential to treat a renal flare.

We continue to believe that Riquent has many potential advantages in the treatment of lupus, most uniquely the possibility of being both efficacious and well tolerated. The unmet medical need in the treatment of lupus is very large, and current therapies have serious side effects and limitations.

### STRONGER PATENT POSITION

We successfully extended our patent portfolio for Riquent as new composition of matter patents were granted in Europe and China. In the U.S. and Europe, with full-term extension, our composition patents will not expire until 2018 or 2019. We also have Orphan Drug status in the U.S. and in Europe.

#### **BEYOND RIQUENT**

We also have developed highly targeted inhibitors of SSAO, an enzyme involved in inflammation. Our SSAO inhibitors are orally active small molecules that could be used to treat autoimmune diseases and inflammatory disorders. We have generated encouraging results in animal models of diseases such as rheumatoid arthritis, multiple sclerosis, inflammatory bowel disease, stroke, and acute inflammation. We continue to explore partnerships, joint ventures, and other avenues for funding the clinical development of our SSAO inhibitors.

#### AS WE PROGRESS: A SINCERE THANK YOU

Our journey to bring Riquent to market is near the final stretch. Each of our stockholders can feel confident that our employees, individually and as a team, are dedicated to achieving this critical goal. Their unrelenting commitment, and the support of our clinicians, lupus patients, and our stockholders, give us the confidence and resolve to reach our objective.

Sincerely,

Deirdre Y. Gillespie, M.D.

Down allow

President & CEO

Craig R. Smith, M.D.

Chairman of the Board

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

## **FORM 10-K**

☑	ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934					
	For the fiscal year ended DECEMBER 31, 20	007				
		OR				
	ECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT					
	For the transition period fromto					
	Commission	file number: 0-24274				
I	LA JOLLA PHARMA (Exact name of regis	ACEUTICAL COMPANY strant as specified in its charter)				
	Delaware (State or other jurisdiction of incorporation or organization)	33-0361285 (I.R.S. Employer Identification Number)				
		Drive, San Diego, CA 92121 ecutive offices, including Zip Code)				
	Registrant's telephone numb	er, including area code: (858) 452-6600				
	Securities registered pursu	ant to Section 12(b) of the Act: None				
	Securities registered pu	rsuant to Section 12(g) of the Act:				
	Title of each class: Common Stock, par value \$0.01 per share	Name of each exchange on which registered: The Nasdaq Global Market				
Inc	licate by check mark if the registrant is a well-known	seasoned issuer, as defined in Rule 405 of the Securities Act. Yes □ No ☑				
Inc	licate by check mark if the registrant is not required	to file reports pursuant to Section 13 or 15(d) of the Act. Yes $\square$ No $\boxtimes$				
Securit	licate by check mark whether the registrant: (1) has fittes Exchange Act of 1934 during the preceding 12 meth reports), and (2) has been subject to such filing recommendations.	Tiled all reports required to be filed by Section 13 or 15(d) of the nonths (or for such shorter period that the registrant was required to quirements for the past 90 days. Yes ☑ No □				
will no	licate by check mark if disclosure of delinquent filers at be contained, to the best of registrant's knowledge, are in Part III of the Form 10-K or any amendment to	s pursuant to Item 405 of Regulation S-K is not contained herein, and in definitive proxy or information statements incorporated by this Form 10-K.				
smalle	dicate by check mark whether the registrant is a large r reporting company. See the definitions of "large ac to 12b-2 of the Exchange Act. (Check one):	accelerated filer, an accelerated filer, a non-accelerated filer, or a celerated filer," "accelerated filer" and "smaller reporting company"				
Large	accelerated filer ☐ Accelerated filer ☑ (Do no:	Non-accelerated filer ☐ Smaller reporting company ☐ t check if a smaller reporting company)				
Inc	licate by check mark whether the registrant is a shell	company (as defined in Rule 12b-2 of the Exchange Act). Yes □ No ☑				
2007 to	otaled approximately \$120.881,000 based on the clos	ommon stock held by non-affiliates of the registrant as of June 30, sing price of \$4.48 as reported by the Nasdaq Global Market. As of mpany's common stock (\$0.01 par value) outstanding.				

## DOCUMENTS INCORPORATED BY REFERENCE

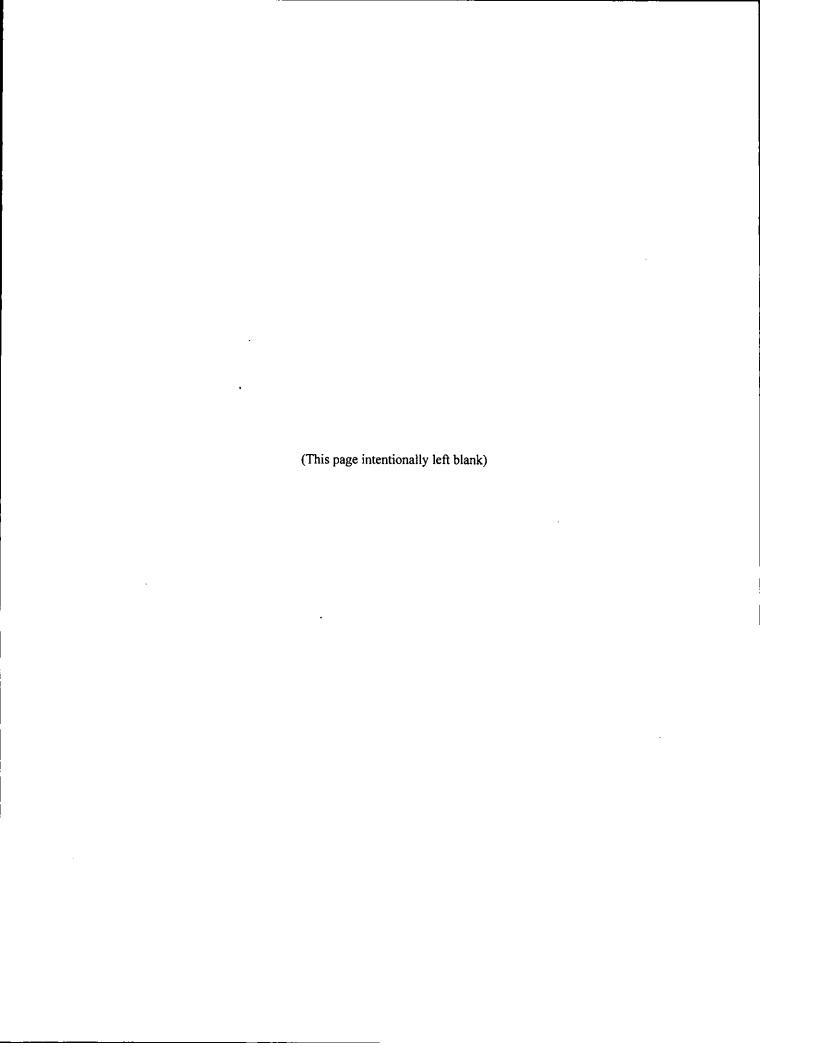
Portions of the annual stockholders' report for the year ended December 31, 2007 are incorporated by reference into Parts 1 and II. Portions of the proxy statement for the 2008 annual stockholders' meeting are incorporated by reference into Part III.

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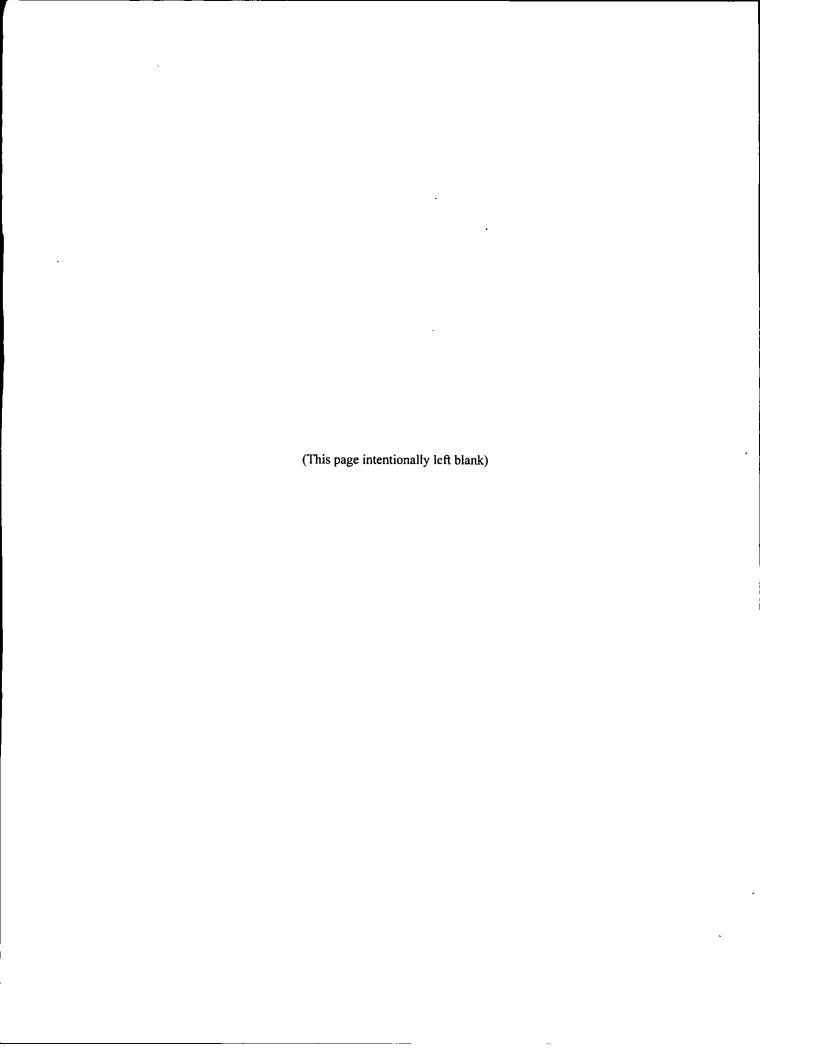
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#### FORWARD-LOOKING STATEMENTS

The forward-looking statements in this report involve significant risks, assumptions and uncertainties, and a number of factors, both foreseen and unforeseen, could cause actual results to differ materially from our current expectations. Forward-looking statements include those that express a plan, belief, expectation, estimation, anticipation, intent, contingency, future development or similar expression. The analyses of clinical results of Riquent® (abetimus sodium), previously known as LJP 394, our drug candidate for the treatment of systemic lupus erythematosus (lupus), and any other drug candidate that we may develop, including the results of any trials or models that are ongoing or that we may initiate in the future, could result in a finding that these drug candidates are not effective in large patient populations, do not provide a meaningful clinical benefit, or may reveal a potential safety issue requiring us to develop new candidates. The analysis of the data from our previous Phase 3 trial of Riquent showed that the trial did not reach statistical significance with respect to its primary endpoint, time to renal flare, or with respect to its secondary endpoint, time to treatment with high-dose corticosteroids or cyclophosphamide. The results from our clinical trials of Riquent, including the results of any trials that are ongoing or that we may initiate in the future, may not ultimately be sufficient to obtain regulatory clearance to market Riquent either in the United States or any other country, and we may be required to conduct additional clinical studies to demonstrate the safety and efficacy of Riquent in order to obtain marketing approval. There can be no assurance, however, that we will have the necessary resources to complete any current or future trials or that any such trials will sufficiently demonstrate the safety and efficacy of Riquent. Our ability to develop and sell our products in the future may be adversely affected by the intellectual property rights of third parties or the validity or enforceability of our intellectual property rights. Additional risk factors include the uncertainty and timing of: our ability to raise additional capital; obtaining required regulatory approvals, including delays associated with any approvals that we may obtain; the timely supply of drug product for clinical trials; our ability to pass all necessary regulatory inspections; the increase in capacity of our manufacturing capabilities for possible commercialization; successfully marketing and selling our products; our lack of manufacturing, marketing and sales experience; our ability to make use of the orphan drug designation for Riquent; generating future revenue from product sales or other sources such as collaborative relationships; future profitability; and our dependence on patents and other proprietary rights. Accordingly, you should not rely upon forward-looking statements as predictions of future events. The outcome of the events described in these forward-looking statements are subject to the risks, uncertainties and other factors described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in the "Risk Factors" contained in this Annual Report on Form 10-K, and in other reports and registration statements that we file with the Securities and Exchange Commission from time to time. We expressly disclaim any intent to update forward-looking statements.



#### PART I

In this report, all references to "we," "our," and "us" refer to La Jolla Pharmaceutical Company, a Delaware corporation, and our wholly owned subsidiary.

#### Item 1. Business

#### Overview

La Jolla Pharmaceutical Company was incorporated in Delaware in 1989. In October 2004, we established a subsidiary, La Jolla Limited, in England in connection with potential development efforts for Riquent® in Europe. We are a biopharmaceutical company dedicated to improving and preserving human life by developing innovative pharmaceutical products. Our leading product in development is Riquent, which is designed to treat patients with lupus. Lupus is an antibody-mediated disease caused by abnormal B cell production of antibodies that attack healthy tissues. Current treatments for this autoimmune disorder often address only symptoms of the disease, or nonspecifically suppress the normal operation of the immune system, which can result in severe, negative side effects and hospitalization. We believe that Riquent has the potential to be an effective lupus therapy without these severe, negative side effects.

#### **Recent Developments**

On February 11, 2008, we announced that we had made significant progress in our current double-blind, placebo-controlled randomized Phase 3 clinical study of Riquent, referred to as the "Phase 3 ASPEN study" (Abetimus Sodium in Patients with a History of Lupus Nephritis), in that we had enrolled 607 patients and 130 clinical trial sites were open to enroll patients in 23 countries. In addition, we also announced that our current enrollment target of at least 740 patients was expected to be completed around the end of the second quarter of 2008.

#### Developments in 2007

On February 1, 2007, we announced that we had made continued progress in enrolling patients in our Phase 3 ASPEN study of Riquent in that we had enrolled 202 patients in the study and 74 clinical trial sites were open to enroll patients, including newly added sites in Europe and Mexico. In addition, we also announced that following recent discussions with the U.S. Food and Drug Administration (the "FDA"), we implemented several enhancements to further strengthen the current Phase 3 ASPEN study, which remains under Special Protocol Assessment. These enhancements included a focus on higher doses and an increase in sample size.

On March 8 and March 20, 2007, we announced positive interim antibody results from our Phase 3 ASPEN study of Riquent. Analyses of interim antibody data indicated that patients treated with 900 mg or 300 mg per week doses of Riquent had greater reductions in antibodies to double-stranded DNA ("dsDNA") than patients treated with 100 mg per week or placebo. The results showed a significant dose response when comparing all Riquent-treated patients to placebo-treated patients (p = 0.0001), and each Riquent dose group to the placebo dose group (p < 0.0032 for 100 mg, p < 0.0001 for 300 mg and 900 mg).

On March 29, 2007, we announced the pricing of an underwritten public offering of 5,800,000 shares of our common stock at \$6.00 per share. In connection with this offering, we granted the underwriters an option to purchase up to an additional 870,000 shares to cover over-allotments. On April 10, 2007, we announced that we had completed the public offering for total net proceeds of approximately \$37.9 million, including the proceeds from the over-allotment shares.

On April 26, 2007, we announced that composition of matter patents covering Riquent were issued in both Europe and in the People's Republic of China. If the full five years of patent term extension under a Supplemental Protection Certificate is granted, the term of the European patent would extend to December 2, 2018. The Chinese patent will be in effect until September 8, 2014.

On May 10, 2007, we announced that Niv E. Caviar had joined the Company as Executive Vice President, Chief Business Officer and Chief Financial Officer.

On May 24, 2007, we announced that we had presented three papers related to Riquent at the 8th International Congress on SLE. The first presentation reviewed recently announced safety and interim antibody data from the Phase 3 ASPEN study which highlighted the statistically significant dose response observed between the 100 mg, 300 mg and 900 mg doses of Riquent compared with placebo (p=0.0001). The second presentation reviewed the safety and drug levels of Riquent at doses of up to 2,400 mg in healthy volunteers and the third, cardiovascular safety in healthy volunteers.

#### **Business Strategy**

Our near term objective is to focus on the development of Riquent, our therapeutic drug candidate for the treatment of lupus renal disease. Additionally, we will also seek to expand our drug development programs. Our strategy includes the following key elements:

Seek additional funding, including through collaborative arrangements and through public and/or private financings, to develop and commercialize product candidates. In order to continue our development and potential commercialization of Riquent and other product candidates, we will need significant additional funding. Our choice of financing alternatives may vary depending on a number of factors, including the interest of other entities in strategic transactions with us, the market price of our securities and conditions in the financial markets. There can be no guarantee that additional financing will be available on favorable terms, if at all, whether through collaborative arrangements, the issuance of securities, or otherwise.

Complete clinical studies of Riquent to satisfy regulatory requirements. Based on the FDA's approvable letter we received in October 2004, we are required to complete an additional, randomized, double-blind study that demonstrates the clinical benefit of Riquent prior to any potential approval in the United States. The letter indicated that the successful completion of our ongoing clinical trial, which we initiated in August 2004, would appear to satisfy this requirement. Our primary goal is to complete this study in order to satisfy the requirement set forth in the FDA's letter. We restarted enrollment in the United States for this study in the third quarter of 2006, after a final review of the revised protocol by the FDA, and expanded the study to Europe and Asia later in 2006. We further expanded the study globally in 2007 and currently target enrolling at least 740 patients, to achieve the required number of renal flares, around the end of the second quarter of 2008.

Continue commercialization planning activities. During 2008, we expect to continue development of a commercialization plan for the United States market including marketing, sales and manufacturing activities. If Riquent is ultimately approved in the United States, as to which we can provide no assurance, we expect to market Riquent ourselves or in collaboration with a commercial partner using a specialty pharmaceutical sales force which would target the rheumatology and nephrology specialists who treat the majority of lupus patients with renal disease. If Riquent is approved outside of the United States, as to which we can provide no assurance, we currently expect to seek a marketing collaboration with one or more partners. We also expect to enter into arrangements with contract manufacturing companies to expand our own production capacity in order to meet potential commercial demand.

Develop additional therapeutics for other life-threatening diseases. We seek to expand our drug development pipeline with products that are commercially synergistic with Riquent by licensing or acquiring rights to compounds and drug candidates that have been developed outside of the Company as well as by collaborating with third parties to further our efforts on drug candidates developed internally.

In recent years, we have focused our product development efforts on our programs for lupus and antiinflammatory disorders. In the years ended December 31, 2007, 2006 and 2005, we incurred expenses of approximately \$46.6 million, \$32.9 million and \$22.6 million, respectively, for product research and development on these programs.

#### Riquent Program

Lupus is a life-threatening, antibody-mediated disease in which disease-causing antibodies damage various tissues. According to recent statistics compiled by the Lupus Foundation of America, epidemiological studies and other sources, the number of lupus patients in the United States is estimated to be between 500,000 and 1,000,000, and approximately 16,000 new cases are diagnosed each year. Approximately nine out of 10 lupus patients are women, who usually develop the disease during their childbearing years. Lupus is characterized by a multitude of symptoms that can include kidney inflammation, which can lead to kidney failure (lupus nephritis), serious episodes of cardiac and central-nervous-system inflammation, as well as extreme fatigue, arthritis and rashes. Approximately 80% of all lupus patients progress to serious symptoms. Approximately 40-45% of lupus patients will develop kidney disease, which is a leading cause of death in lupus.

Antibodies to dsDNA can be detected in up to 85% of lupus patients who are not receiving immunosuppressive therapy. Antibodies to dsDNA are widely believed to cause kidney disease (nephritis), often resulting in morbidity and mortality in lupus patients. Lupus nephritis is characterized by periods of extreme, acute inflammation called "renal flares" which often require aggressive treatment with high-dose corticosteroids, immunosuppressive agents, and hospitalization. Patients not experiencing a renal flare often have less severe, chronic inflammation which can also contribute to the morbidity and mortality of lupus nephritis. Patients experiencing a renal flare have more severe inflammation as evidenced by indicators of diminished kidney function such as elevated serum creatinine or increased proteinuria. Proteinuria, or protein in the urine, is believed to be a pathological indicator of renal disease. The reduction of proteinuria is one of the goals for the treatment of lupus patients with renal disease. Monitoring the level of a patient's proteinuria is a routine and important way to help determine the severity and progression of renal disease. Over time, lupus nephritis can lead to deterioration of kidney function and to end-stage kidney disease, requiring long-term renal dialysis or kidney transplantation to sustain a patient's life.

Current treatments for lupus patients who have a renal flare often involve repeated administration of corticosteroids, often at high levels, that can lead to serious side effects when used long-term. Many patients with renal flares are also treated with immunosuppressive therapy, including anti-cancer or transplantation drugs, which can have a general suppressive effect on the immune system, may be carcinogenic and/or can cause birth defects. Treatment with immunosuppressive therapies can leave patients vulnerable to serious infection, which is a significant cause of sickness and death in these patients. Importantly, many patients do not respond adequately to treatment with immunosuppressive therapies and fail to achieve full remission, a return to normal renal function or the level of renal function prior to the flare. As a result, low to moderate levels of inflammation remain as evidenced by elevated urine protein (proteinuria), elevated serum creatinine, and other markers of abnormal kidney function. This incomplete response to treatment with immunosuppressive therapies increases the risk of additional renal flares as well as the risk of end-stage kidney disease and death.

Riquent was developed based on our patented Tolerance Technology® and comprises a lupus disease specific epitope attached to a carrier platform. The family of molecules based on this technology are called Toleragens®. The design of Riquent is based on scientific evidence of the role of antibodies to dsDNA in lupus. We have designed Riquent to suppress the production of antibodies to dsDNA in lupus patients without suppressing the normal function of the immune system. Published studies of lupus patients indicate that a rise in the level of antibodies to dsDNA may be predictive of renal flares in lupus patients with renal involvement, and that reducing antibodies to dsDNA by treating with corticosteroids can prevent relapse. Furthermore, based on published data from our own previous studies, a reduction in the levels of antibodies to dsDNA significantly correlated with a reduced risk of renal flare and improved health-related quality of life. Based on these same published data, a rise in antibodies to dsDNA significantly correlated with an increased risk of renal flare and no change or deterioration in health-related quality of life. In a mouse model of lupus nephritis that generates elevated levels of antibodies to dsDNA, administration of Riquent reduced the production of antibodies to dsDNA, reduced the number of antibody-forming cells, reduced kidney disease and extended the life of the animals.

We believe that our own and other studies provide evidence that reducing levels of antibodies to dsDNA may provide an effective therapy for lupus nephritis. Based on this rationale, the Phase 3 ASPEN study is designed to assess the ability of Riquent to provide or maintain a remission in lupus nephritis. This is evidenced by the prevention of renal flares and by reductions in proteinuria, which are both important measures of damage to the kidney leading to abnormal kidney function.

#### Riquent Clinical Trial History

#### Phase 1 trial

Based on our pre-clinical findings, we filed an Investigational New Drug application for Riquent with the FDA in August 1994. In a double-blind, placebo-controlled Phase 1 clinical trial conducted in December 1994, healthy volunteers received Riquent and displayed no drug-related adverse effects. Upon completion of our Phase 1 trial, we began four Phase 2 clinical trials.

#### Phase 2 trials

Our Phase 2 clinical trials included a single-dose trial, a repeat dose-escalating trial and two dose-ranging trials.

In 1994, we initiated a single-dose clinical trial to evaluate the safety of a single, 100 mg intravenous dose of Riquent in four female lupus patients. Riquent was well tolerated by all four patients, with no drug-related adverse clinical symptoms and no clinically significant complement (inflammation-promoting proteins) level changes.

In 1995, we initiated a repeat dose-escalating clinical trial in which two female lupus patients each received doses of 10, 10, 50, 50, 100 and 100 mg of Riquent at two-week intervals. After the 10-week dosing regimen was completed, the patients were monitored for six weeks. Riquent was well tolerated by both patients. Six weeks after the last dose, the antibodies to dsDNA levels in both patients remained suppressed below baseline levels.

Also in 1995, we conducted a double-blind, placebo-controlled dose-ranging trial, in which 58 lupus patients with mild lupus symptoms were treated for a four-month period with Riquent or placebo, and then were monitored for two months. Patients in the weekly treatment groups showed a dose-response correlation between increasing doses of Riquent and reductions of levels of antibodies to dsDNA. The drug was well tolerated with no clinically significant dose-related adverse reactions observed.

In 1999, we completed a second double-blind, placebo-controlled dose-ranging trial, in which 74 lupus patients received weekly injections of 10, 50 or 100 mg of Riquent or placebo for a 12-week period. In patients treated weekly with placebo, 10 mg or 50 mg of Riquent, antibodies to dsDNA increased by 100%, 53% and 10%, respectively, while in patients treated weekly with 100 mg of Riquent, antibodies to dsDNA decreased by 43%, a statistically significant difference from placebo. Seven Riquent-treated patients had serious adverse events, but none were considered related to Riquent treatment.

#### Phase 2/3 trial

In December 1996, we initiated a double-blind, placebo-controlled, multi-center Phase 2/3 clinical trial of Riquent in which lupus patients with a history of lupus nephritis received placebo or weekly doses of 100 mg of Riquent for the first 16 weeks of the trial. The trial design was then changed whereby, patients received alternating eight week drug holidays followed by 12 weeks of weekly treatments with 50 mg of Riquent or placebo. Patients were in the trial for up to 18 months. More than 200 patients at more than 50 sites in North America and Europe enrolled in the trial. This trial was conducted with Abbott Laboratories as part of our former joint development agreement.

In May 1999, an interim analysis of the Phase 2/3 trial indicated that the trial was unlikely to reach statistical significance for the primary endpoint, time to renal flare, and the trial was stopped. In September 1999, our joint development agreement for Riquent with Abbott Laboratories was terminated.

In November 1999, we announced results from retrospective analyses of the data from the Phase 2/3 clinical trial, which showed that a certain group of patients treated with Riquent with "high affinity" antibodies had fewer renal flares and longer time to treatment with high-dose corticosteroids and/or cyclophosphamide ("HDCC"). These results were based on an analysis of the trial using a blood test that we developed and that appears to predict which patients will respond to treatment with Riquent at the doses being administered at that time.

The "high-affinity" patients treated with Riquent experienced significantly longer time to renal flare (p = 0.007), the primary endpoint of the trial, fewer renal flares (p = 0.008), longer time to treatments with HDCC (p = 0.0003) and fewer exposures to HDCC (p < 0.001) when compared to the placebo-treated group. Also in the Phase 2/3 trial, mean levels of circulating antibodies to dsDNA in patients treated with Riquent were reduced by a statistically significant amount relative to placebo during drug treatment (p < 0.0001). Further, in a group of high-affinity patients with impaired renal function (defined as serum creatinine  $\geq 1.5$  mg/dL), there were six renal flares in 11 patients treated with Placebo and no renal flares in 11 patients treated with Riquent (p = 0.012).

#### Previous Phase 3 trial

Based on the observations from our Phase 2/3 trial and following discussions with the FDA, we initiated a Phase 3 clinical trial in September 2000 to further evaluate the safety and efficacy of Riquent in the treatment of lupus renal disease. The double-blind, placebo-controlled study was conducted at 91 sites in North America and Europe and was designed to evaluate the potential of Riquent to delay and reduce the number of renal flares and to delay and reduce the need for treatment with HDCC and/or other immunosuppressive drugs in high-affinity patients. Patients in the trial were treated weekly with either 100 mg of Riquent or placebo for a period of up to 22 months.

Following the completion of the trial in February 2003, we announced that Riquent appeared to be well tolerated with no apparent differences in the overall incidence of serious adverse events or adverse events between Riquent-treated and placebo-treated patients. The trial data indicated that treatment with Riquent did not increase length of time to renal flare, the primary endpoint, or time to treatment with HDCC, the secondary endpoint, in a statistically significant manner when compared with placebo through the end of the study.

In the trial, there were fewer renal flares, fewer treatments with HDCC and fewer Major SLE flares in Riquent-treated patients compared with placebo-treated patients, but the differences were not statistically significant. There was a 25% reduction in the incidence of renal flare and a 21% reduction in the incidence of Major SLE flare. The estimated median time to renal flare was 123 months in the Riquent-treated group and 89 months in the placebo-treated group. There was a statistically significant reduction in antibodies to dsDNA in the Riquent-treated group compared with the placebo-treated group (p < 0.0001). In patients with impaired renal function at baseline, Riquent-treated patients had fewer renal flares, treatments with HDCC and Major SLE flares compared with patients on placebo, but the sample size of this subgroup was small and the differences were not statistically significant.

In March 2003, we announced results from several retrospective analyses of trial data indicating that renal flares occurred approximately one-fifth as often in patients with sustained reductions in antibodies to dsDNA compared with patients with unchanged or increasing antibodies (Phase 3: p < 0.0001; Phase 2/3: p = 0.0004). Patients with sustained reductions in antibodies to dsDNA also reported improved or maintained health-related quality of life compared with patients that did not have sustained reductions, regardless of treatment group. In November 2003, we announced analyses using Cox's Proportional Hazards Regression Model demonstrating that a 50% reduction in antibodies to dsDNA from baseline was associated with a 52% lower risk of renal flare in the Phase 2/3 trial (p = 0.0007) and a 53% lower risk in the Phase 3 trial (p < 0.0001).

Further, in March 2004, we announced statistically significant but retrospective results from the Phase 2/3 and Phase 3 trials showing that, after one year of treatment, the proportion of lupus patients with a reduction in proteinuria of at least 50% from baseline was significantly greater in the Riquent-treated group than in the placebotreated group.

In 2004, we filed a New Drug Application ("NDA") for Riquent with the FDA. Our NDA submission was prepared on our understanding that the FDA could potentially approve Riquent on the basis of our clinical trial results or under the accelerated approval regulation known as Subpart H. Under Subpart H, drugs in development for serious, life-threatening diseases with an unmet medical need can be approved on an accelerated basis if the FDA determines that the effect of the drug on a surrogate endpoint is reasonably likely to predict clinical benefit and that a post-marketing clinical trial can be successfully completed following drug approval which confirms the clinical benefit. As previously described, in our Phase 3 and Phase 2/3 trials, patients treated with Riquent had significantly reduced levels of antibodies to dsDNA compared with patients treated with placebo. In October 2004, we received a letter from the FDA indicating that Riquent is approvable, but that an additional, randomized, double-blind study demonstrating the clinical benefit of Riquent would need to be completed prior to approval. The FDA letter indicated that the successful completion of the clinical trial that we initiated in August 2004 would appear to satisfy this requirement.

#### Current Phase 3 ASPEN trial

A placebo controlled Phase 3 clinical benefit trial, designed to meet the FDA's requirement that we conduct an additional randomized, double-blind study, was initiated in August 2004 under a Special Protocol Assessment ("SPA"). The SPA process is a formal procedure that results in a binding written agreement between a company and the FDA concerning the design of a clinical trial or other study. While we delayed additional patient enrollment in March 2005 to conserve cash, in the third quarter of 2006 we reinitiated enrollment in the trial and, on February 11, 2008, announced that 607 patients had been enrolled in the study and 130 clinical trial sites were open to enroll patients in 23 countries. Our current enrollment target of at least 740 patients is expected to be completed around the end of the second quarter of 2008.

In the current Phase 3 ASPEN trial compared to the previous Phase 3 study, virtually all patients are being treated with one of two higher doses of Riquent or placebo, the number of patients to be studied was more than doubled, the primary endpoint was refined, the use of immunosuppressive agents was further restricted, and the treatment duration was changed to 12 months. As in the previous Phase 3 study, patients in the current study all have a history of lupus renal disease. The primary endpoint, time to renal flare, was refined in order to eliminate the hematuria component, which appears to be less specific for lupus renal disease. These changes were all based on results of the previous Phase 2/3 and Phase 3 trials of Riquent. Secondary endpoints in the current Phase 3 ASPEN study include reduction in proteinuria, an indicator of renal function, as well as time to major SLE flare, a measure of SLE disease activity.

On February 1, 2007, following further discussions with the FDA, we announced that all new patients entering the study will be randomized in equal numbers to receive weekly doses of either 300 mg or 900 mg of Riquent or placebo, with no further patients randomized to the 100 mg dose group. Currently, approximately 50 patients are being treated with 100 mg and will continue at that dose through the completion of the study. The FDA confirmed that the primary endpoint required to establish efficacy is the time to renal flare for the combined population of patients treated with weekly Riquent doses of 300 mg and 900 mg, compared with placebo.

This study is an event-driven trial requiring us to accrue a specified number of renal flares to complete the study. We currently target enrolling at least 740 patients to achieve the required number of renal flares. The study's sample size has been increased to at least 740 patients, which is expected to increase the likelihood of achieving a statistically significant outcome for the overall dose group as well as individual dose groups when compared with placebo. The number of patients targeted to be enrolled is more than twice the approximately 300 patients in the previous Phase 3 study. The trial design is based on the results from the last Phase 3 study, where all drug-treated patients received a dose of 100 mg per week of Riquent. In determining how many patients should be enrolled in the current Phase 3 ASPEN study, no additional clinical benefit from treatment with the higher doses was assumed.

In other changes to the study design, the study entry criteria further restricts the use of immunosuppressive agents that, in the previous Phase 3 study, may have reduced the renal flare rate. Also, the current design was changed to a fixed 12-month patient evaluation period. In the previous Phase 3 trial, patients were treated for up to 22 months.

Also, the primary endpoint will be assessed in all patients and will no longer be restricted to the high-affinity subpopulation. We believe that the increased binding capability of higher doses will eliminate the need for an affinity measurement prior to treatment.

To increase efficiency and enhance the quality of data, we also combined the Phase 2 clinical pharmacokinetic study with the Phase 3 ASPEN study so that Riquent blood levels will be collected in the same patient population as the definitive efficacy data. These changes were all incorporated into the approved SPA.

Previously, in January 2006, we had reached an agreement with the FDA to assess the dose response of the treatment with Riquent on antibodies to dsDNA by conducting an interim analysis to evaluate the effect of higher doses on the reduction of these antibodies. In March 2007, we performed an interim antibody analysis of our current Phase 3 ASPEN study of Riquent. The analyses assessed the impact of treatment with Riquent eight weeks after the start of treatment on reducing antibodies to dsDNA in 101 patients by measuring the percent of antibody reduction from baseline compared with placebo following weekly treatment with 100 mg, 300 mg or 900 mg of Riquent or placebo. All demographics and baseline characteristics were comparable across dosing groups and there were 16 to 30 patients per treatment group.

The analyses of interim antibody data indicated that patients treated with 900 mg or 300 mg per week doses of Riquent had greater reductions in antibodies to dsDNA than patients treated with 100 mg per week or placebo. The results showed a significant dose response when comparing all Riquent-treated patients to placebo-treated patients (p < 0.0001), and each Riquent dose group to the placebo dose group (p < 0.0015 for 100 mg, p < 0.0001 for 300 mg and 900 mg).

The median percent reduction in antibodies to dsDNA for Riquent-treated patients compared with placebotreated patients was 36% (100 mg), 48% (300 mg), and 66% (900 mg). Antibody reduction for each dose group was significantly better than placebo. Approximately three times as many patients treated with 900 mg of Riquent (38%) had at least a 50% or greater antibody reduction at week 8 compared with patients treated with 100 mg (13%). Patients reached their maximum reduction after four weeks of treatment at which time separation between doses was also seen.

As indicated in our earlier studies, maintaining antibody reductions over time in individual patients was associated with a significantly reduced renal flare rate. The data from the interim antibody analysis indicate that the higher the Riquent dose, the greater the consistency of response and the greater the magnitude of this response. While more than twice as many 900 mg-treated patients (58%) as 100 mg-treated patients (25%) had a consistent 20% reduction, six times as many 900 mg-treated patients (39%) had a consistent 40% reduction, compared with 100 mg-treated patients (6%). Twice as many patients on 900 mg as 300 mg had a consistent 50% reduction, but no patients on 100 mg or placebo achieved this level of consistent reduction. A consistent reduction is defined as a patient whose percent antibody reduction exceeded a specified level at weeks 4, 6 and 8.

To date, Riquent has been well tolerated in the current Phase 3 ASPEN study with no overall difference in the adverse event profiles for Riquent-treated patients compared with placebo-treated patients. Furthermore, the adverse event profile for all patients in the study to date, including those treated with the 300 mg and 900 mg doses, does not appear to differ from that seen in previous studies where 100 mg of Riquent was the treatment dose. As of February 11, 2008, more than 350 patients have been treated in the trial with either the 300 mg or 900 mg dose.

We also plan to conduct two interim efficacy analyses. The first interim efficacy analysis is expected to occur around the end of the second quarter of 2008 and the second interim efficacy analysis is expected to occur around the end of 2008. The overall statistical significance level of the study for testing the primary endpoint is adjusted for these interim analyses.

To assess the tolerability of higher doses, a safety study in healthy volunteers was completed in 2005. Subjects received a single dose of Riquent at 600 mg, 1200 mg, or 2400 mg. Riquent appeared to be well tolerated in these subjects.

Riquent Regulatory Status

#### Orphan drug designation for Riquent

In September 2000, the FDA granted us orphan drug designation for Riquent for the treatment of lupus nephritis. The Orphan Drug Act potentially enables us to obtain research funding, tax credits for certain research expenses and a waiver of the application user fees. In addition, the Orphan Drug Act allows for seven years of exclusive marketing rights to a specific drug for a specific orphan indication. Exclusivity is conferred upon receipt of marketing approval from the FDA to the first sponsor who obtains such approval for a designated drug. The marketing exclusivity prevents FDA approval during the seven-year period of the "same" drug, as defined in the FDA regulations, from another company for the same orphan indication. Whether we will be able to take advantage of some of the benefits afforded by the orphan drug designation will ultimately be determined by the FDA only after further review of our NDA.

In November 2001, the European Commission granted us orphan medicinal product designation in the European Union for Riquent for the treatment of lupus nephritis. Orphan designation in Europe provides for 10 years of marketing exclusivity in the European Union and enables us to receive significant fee reductions for scientific advice from the Committee for Orphan Medicinal Products, marketing authorization and inspections.

#### FDA fast track designation for Riquent

In May 2005, the FDA granted fast track designation for Riquent for the treatment of lupus renal disease. The FDA's fast track program is designed to facilitate the development and to expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address an unmet medical need.

#### **Inflammatory and Autoimmune Programs**

#### SSAO Inflammation Program

Because substantially all of our resources are currently being devoted to the development of Riquent, further development of the SSAO program depends on our ability to obtain third-party financing for this program through a joint venture, partnership or other collaborative arrangement on acceptable terms to us.

On December 2, 2003, we announced the discovery of novel, orally-active small molecules for the treatment of autoimmune diseases and acute and chronic inflammatory disorders. Our scientists have generated highly selective inhibitors of SSAO, an enzyme that has been implicated in inflammatory responses in many tissues and organs. SSAO, also known as vascular adhesion protein-1 or VAP-1, was recently discovered to be a dual-function molecule with enzymatic and cell adhesion activities. SSAO on blood vessels contributes to inflammation by helping white blood cells leave the blood and penetrate inflamed tissue. The enzyme also contributes to the production of molecules that exacerbate inflammation, including formaldehyde and oxygen free radicals. SSAO inhibitors are designed to reduce inflammation by blocking the white blood cells and reducing the levels of inflammatory mediators.

Increases in the levels of plasma or membrane-associated SSAO have been reported for many inflammation-associated diseases including rheumatoid arthritis, inflammatory bowel disease, diabetes, atherosclerosis psoriasis and chronic heart failure. In addition, treatment of animals with SSAO inhibitors has been shown to provide significant benefit in several inflammation-based diseases.

Data published by our scientists in 2005 and 2006 in peer-reviewed articles show that these novel, orally-active small molecule inhibitors of SSAO/VAP-1 may provide clinical benefit for the treatment of stroke, ulcerative colitis, and other autoimmune diseases and inflammatory disorders. Peer-reviewed data published in 2007 identified and characterized a lead compound and described its role in inhibiting inflammation in the lungs of rodents.

#### **Collaborative Arrangements**

In circumstances where we believe that a collaborative agreement is necessary or strategically beneficial to us, we intend to pursue collaborative arrangements with other pharmaceutical companies to assist in our research programs and the clinical development and commercialization of our drug candidates and to access their research, drug development, manufacturing, marketing and financial resources. There can be no assurance that we will be able to negotiate arrangements with any collaborative partner on acceptable terms, or at all. If a collaborative relationship is established, there can be no assurance that the collaborative partner will continue to fund any particular program or that it will not pursue alternative technologies or develop alternative drug candidates, either individually or in collaboration with others, including our competitors, as a means for developing treatments for the diseases we have targeted. Furthermore, competing products, either developed by a collaborative partner or to which a collaborative partner has rights, may result in the withdrawal of support by the collaborative partner with respect to all or a portion of our technology.

Failure to establish or maintain collaborative arrangements will require us to fund our own research and development activities, resulting in significant expenditure of our own capital, and will require us to develop our own marketing capabilities for any drug candidate that may receive regulatory approval. The failure of any collaborative partner to continue funding any particular program, or to commercialize successfully any product, could delay or halt the development or commercialization of any products involved in such program. As a result, the failure to establish or maintain collaborative arrangements could hurt our business, financial condition and results of operations.

#### Manufacturing

We currently operate a production facility that we believe provides sufficient capacity to meet our anticipated requirements for research, clinical trial and any initial commercial launch of Riquent. If Riquent is approved, we expect to have the capacity to manufacture approximately 100 kg of Riquent per year. If Riquent is approved, and if future demand for Riquent exceeds our current capacity, we expect to increase our manufacturing capacity by improving our manufacturing processes, making capital investments in our current facilities and engaging third party contract manufacturers.

We are required to comply with the FDA's and other regulatory agencies' current Good Manufacturing Practices ("cGMPs") when we manufacture our drug candidates for clinical trials. We will also be required to comply with the cGMPs if Riquent, or our other drug candidates, are manufactured for commercial purposes. We have limited manufacturing experience and we can provide no assurance that we will be able to successfully transition to commercial production.

In order to meet the demand for any of our drugs that may be approved or to attempt to improve our manufacturing efficiency, we may enter into arrangements with third party contract manufacturers. If we choose to contract for manufacturing services, the FDA and comparable foreign regulators will have to approve the contract manufacturers prior to our use, and these contractors would be required to comply with strictly enforced manufacturing standards. Currently, we also enter into agreements with contractors to prepare our drug candidates for use by patients. If we encounter delays or difficulties in establishing or maintaining relationships with contractors to produce, package or distribute finished products, clinical trials, market introduction and subsequent sales of such products would be adversely affected. Our dependence on others for production, packaging or distribution of our products may adversely affect our profit margins and our ability to develop and deliver our products on a timely and competitive basis.

There are currently a limited number of suppliers that produce the raw materials that are necessary to make Riquent. In order to manufacture Riquent in sufficient quantities for our clinical trials and possible commercialization, our suppliers will be required to provide us with an adequate supply of chemicals and reagents. If we are unable to obtain sufficient quantities of chemicals or reagents, our ability to develop and deliver products on a timely and competitive basis will be negatively affected.

#### Marketing and Sales

If we obtain FDA approval in the United States, we currently anticipate that we would market Riquent ourselves or in collaboration with a commercial partner using a specialty pharmaceutical sales force of 40 to 60 sales representatives who would initially target the rheumatology and nephrology specialists who treat the majority of lupus patients with renal disease. We estimate that the majority of these patients are treated by 3,000 lupus specialty physicians primarily at approximately 1,000 clinical centers. If we obtain approval outside of the United States, we currently expect to seek a marketing collaboration with a partner.

While we are actively seeking a marketing collaboration with a partner, we currently have no arrangements with others for the marketing of any of our drug candidates. There can be no assurance that we will be able to enter into any marketing agreements on favorable terms, if at all, or that any such agreements that we may enter into will result in payments to us. Under any co-promotion or other marketing and sales arrangements that we may enter into with other companies, any revenues that we may receive will be dependent on the efforts of others and there can be no assurance that such efforts will be successful.

To the extent that we choose to attempt to develop our own marketing and sales capability (whether domestic or international), we will compete with other companies that have experienced and well-funded marketing and sales operations. Furthermore, there can be no assurance that we, or any collaborative partner, will be able to establish sales and distribution capabilities without undue delays or expenditures, or gain market acceptance for any of our drug candidates. The ultimate size of the markets for our products is uncertain and difficult to estimate. Moreover, we may not earn as much income as we hope due to possible changes in healthcare reimbursement policies by governments and other third party payers.

#### Patents and Proprietary Technologies

We file patent applications in the United States and in foreign countries for the protection of our proprietary technologies and drug candidates as we deem appropriate. We currently own 135 issued patents and have 40 pending patent applications in the United States and in foreign countries covering various technologies and drug candidates, including our lupus drug candidates (Toleragens), our SSAO inhibitor technology (currently there are no issued patents to our SSAO inhibitor technology), our antibody-mediated thrombosis drug candidates (Toleragens), our Tolerance Technology, and our carrier platform and linkage technologies for our Toleragens. Our issued patents include:

- Lupus Toleragens seven issued United States patents, three issued Australian patents, one granted Portuguese patent, two granted Norwegian patents, one granted European patent (which has been unbundled as 13 European national patents), a second granted European patent (which has been unbundled as 15 European national patents), two granted Chinese patents, one granted Hong Kong patent, one granted South Korean patent, two granted Canadian patents, two granted Finnish patents, one granted Irish patent, and one granted Japanese patent (expiring between 2010 and 2020); and
- Tolerance Technology five issued United States patents, one issued Australian patent, one granted European patent (which has been unbundled as 15 European national patents), one granted Japanese patent, two granted Canadian patents, one granted South Korean patent and one granted Irish patent (expiring between 2011 and 2012).

## Competition

The biotechnology and pharmaceutical industries are subject to rapid technological change. Competition from domestic and foreign biotechnology companies, large pharmaceutical companies and other institutions is intense and expected to increase. A number of companies are pursuing the development of pharmaceuticals in our targeted areas. These include companies that are conducting clinical trials and pre-clinical studies for the treatment of lupus.

In addition, there are a number of academic institutions, both public and private, engaged in activities relating to the research and development of therapeutics for autoimmune, inflammatory and other diseases. Most of these companies and institutions have substantially greater facilities, resources, research and development capabilities, regulatory compliance expertise, and manufacturing and marketing capabilities than we do. In addition, other technologies may in the future be the basis of competitive products. There can be no assurance that our competitors will not develop or obtain regulatory approval for products more rapidly than we can, or develop and market technologies and products that are more effective than those we are developing or that would render our technology and proposed products obsolete or noncompetitive.

Many of the currently used pharmacological interventions along with new drugs in development for lupus are broad based immunosuppresants that cause varying degrees of toxicity and tolerability issues for patients. Riquent is designed to be highly specific by targeting antibodies to dsDNA. Additionally, Riquent is one of the few drugs being studied as a therapy to maintain remission of lupus nephritis. We believe that our ability to compete successfully will depend on our ability to secure additional capital resources to fund anticipated net losses for at least the next several years, develop patented or proprietary technologies and products, obtain regulatory approvals, effectively manufacture and market products either alone or through third parties, and attract and retain experienced scientists. If Riquent is commercialized, we expect that competition among marketed products will be based in large part on product safety, efficacy, reliability, availability, price and patent position.

#### Government Regulation

#### **United States**

Our research and development activities and the future manufacturing and marketing of any products we develop are subject to significant regulation by numerous government authorities in the United States and other countries. In the United States, the Federal Food, Drug and Cosmetic Act and the Public Health Service Act govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion, and distribution of our drug candidates and any products we may develop. In addition to FDA regulations, we are subject to other federal, state and local regulations, such as the Occupational Safety and Health Act and the Environmental Protection Act, as well as regulations governing the handling, use and disposal of radioactive and other hazardous materials used in our research activities. Product development and approval within this regulatory framework takes a number of years and involves the expenditure of substantial resources. In addition, this regulatory framework is subject to changes that may adversely affect approval, delay an application or require additional expenditures.

The steps required before a pharmaceutical compound may be marketed in the United States include: preclinical laboratory and animal testing; submission to the FDA of an Investigational New Drug application, which must become effective before clinical trials may commence; conducting adequate and well-controlled clinical trials to establish the safety and efficacy of the drug; submission to the FDA of an NDA or Biologic License Application ("BLA") for biologics; satisfactory completion of an FDA preapproval inspection of the manufacturing facilities to assess compliance with cGMPs; and FDA approval of the NDA or BLA prior to any commercial sale or shipment of the drug. In addition to obtaining FDA approval for each product, each drug-manufacturing establishment must be registered with the FDA and be operated in conformity with cGMPs. Drug product manufacturing facilities located in California also must be licensed by the State of California in compliance with separate regulatory requirements.

Pre-clinical testing includes laboratory evaluation of product chemistry and animal studies to assess the safety and efficacy of the product and its formulation. The results of pre-clinical testing are submitted to the FDA as part of an Investigational New Drug Application and, unless the FDA objects, the Investigational New Drug Application becomes effective 30 days following its receipt by the FDA.

Clinical trials involve administration of the drug to healthy volunteers and to patients diagnosed with the condition for which the drug is being tested under the supervision of a qualified clinical investigator. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety, and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the Investigational New Drug application. Each clinical trial is conducted under the auspices of an independent Institutional Review Board ("IRB") in the United States or Ethics Committee ("EC") outside the United States for each trial site. The IRB or EC considers, among other matters, ethical factors and the safety of human subjects.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap or be repeated. In Phase 1, the phase in which the drug is initially introduced into healthy human subjects or patients, the drug is tested for adverse effects, dosage tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase 2 trials involve the testing of a limited patient population in order to characterize the actions of the drug in targeted indications, to determine drug tolerance and optimal dosage, and to identify possible adverse side effects and safety risks. When a compound appears to be effective and to have an acceptable safety profile in Phase 2 clinical trials, Phase 3 clinical trials are undertaken to further evaluate and confirm clinical efficacy and safety within an expanded patient population at multiple clinical trial sites. The FDA reviews the clinical plans and monitors the results of the trials and may discontinue the trials at any time if significant safety issues arise. Similarly, an IRB may suspend or terminate a trial at a study site which is not being conducted in accordance with the IRB's requirements or which has been associated with unexpected serious harm to subjects.

The results of pre-clinical testing and clinical trials are submitted to the FDA in the form of an NDA or BLA for marketing approval. The submission of an NDA or BLA also is subject to the payment of user fees, but a waiver of the fees may be obtained under specified circumstances. The testing and approval process is likely to require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all, or that conditions of any approval, such as warnings, contraindications, or scope of indications will not materially

impact the potential market acceptance and profitability of the drug product. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it generally follows such recommendations. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments, and the risks and benefits of the product demonstrated in clinical trials.

Additional pre-clinical testing or clinical trials may be requested during the FDA review period and may delay any marketing approval. After FDA approval for the initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications. In addition, after approval, some types of changes to the approved product, such as manufacturing changes, are subject to further FDA review and approval. The FDA mandates that adverse effects be reported to the FDA and may also require post-marketing testing to monitor for adverse effects, which can involve significant expense. Adverse effects observed during the commercial use of a drug product or which arise in the course of post-marketing testing can result in the need for labeling revisions, including additional warnings and contraindications, and, if the findings significantly alter the risk/benefit assessment, the potential withdrawal of the drug from the market.

Among the conditions for FDA approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the FDA's cGMP requirements. Domestic manufacturing facilities are subject to biannual FDA inspections and foreign manufacturing facilities are subject to periodic inspections by the FDA or foreign regulatory authorities. If the FDA finds that a company is not operating in compliance with cGMPs, the continued availability of the product can be interrupted until compliance is achieved and, if the deficiencies are not corrected within a reasonable time frame, the drug could be withdrawn from the market. In addition, the FDA strictly regulates labeling, advertising and promotion of drugs. Failure to conform to requirements relating to licensing, manufacturing, and promoting drug products can result in informal or formal sanctions, including warning letters, injunctions, seizures, civil and criminal penalties, adverse publicity and withdrawal of approval.

#### **Foreign**

We are also subject to numerous and varying foreign regulatory requirements governing the design and conduct of clinical trials and marketing approval for pharmaceutical products to be marketed outside of the United States. The approval process varies among countries and regions and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval.

The steps to obtain approval to market Riquent in the European Union include: pre-clinical laboratory and animal testing; conducting adequate and well controlled clinical trials to establish safety and efficacy; submission of a Marketing Authorization Application (the "MAA"); and the issuance of a product marketing license by the European Commission prior to any commercial sale or shipment of drug. In addition to obtaining a product marketing license for each product, each drug manufacturing establishment must be registered with the European Medicines Agency (the "EMEA") must operate in conformity with European good manufacturing practice, and must pass inspections by the European health authorities.

Upon receiving the MAA, the Committee for Human Medicinal Products (the "CHMP"), a division of the EMEA, will review the MAA and may respond with a list of questions or objections. The answers to the questions posed by the CHMP may require additional tests to be conducted. Responses to the list of questions or objections must be provided to and deemed sufficient by the CHMP within a defined timeframe. Ultimately, a representative from each of the European Member States will vote whether to approve the MAA.

Foreign regulatory approval processes include all of the risks associated with obtaining FDA approval, and approval by the FDA does not ensure approval by the health authorities of any other country.

#### **Employees**

As of February 29, 2008, we employed 86 regular full-time employees (including seven people who have a Ph.D. and three people who have an M.D., one of which also has a Ph.D.), 68 of whom are involved full-time in clinical, development and manufacturing activities. All members of our senior management team have had prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced personnel, but competition for personnel is intense and there can be no assurance that we will be able to attract and retain the individuals needed. None of our employees are covered by collective bargaining agreements and management considers relations with our employees to be good.

#### **Available Information**

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Exchange Act of 1934, as amended, are available free of charge through our website at www.ljpc.com as soon as reasonably practicable after we electronically file or furnish the reports with or to the Securities and Exchange Commission.

#### Item 1A. Risk Factors

## I. RISK FACTORS RELATING TO LA JOLLA PHARMACEUTICAL COMPANY AND THE INDUSTRY IN WHICH WE OPERATE.

We do not have sufficient financial resources to complete the current Phase 3 ASPEN study of Riquent and may not have sufficient resources to continue to operate unless we are able to raise sufficient additional capital.

We will need to successfully complete the current Phase 3 ASPEN study prior to any FDA or any foreign regulatory approvals. The current Phase 3 ASPEN study is an event-driven trial requiring us to accrue a specified number of renal flares to complete the study. We currently target enrolling at least 740 patients to achieve the required number of renal flares and the trial could take several years to complete. We expect that the actual costs of completing the current Phase 3 ASPEN study will exceed our current cash resources. If we expend all of the funds that we have raised and do not receive funding from a collaborative agreement with a corporate partner or obtain other financing, we would not have the financial resources to complete the current Phase 3 ASPEN study or to continue the development of Riquent, and we may not be able to continue to operate.

We may need to sell stock or assets, enter into collaborative agreements, significantly reduce our operations, or merge with another entity to continue operations.

Our business is highly cash-intensive and we will need a significant amount of additional cash to continue our operations. There can be no guarantee that additional financing will be available to us on favorable terms, or at all, whether through issuance of additional securities, entry into collaborative arrangements, or otherwise. If adequate funds are not available, we may halt the current Phase 3 ASPEN study, significantly reduce the size of our workforce, sell or license our technologies or obtain funds through other arrangements with collaborative partners or others that require us to relinquish rights to our technologies or potential products. We also may merge with another entity to continue our operations. Any one of these outcomes could have a negative impact on our ability to develop products or achieve profitability if our products are brought to market. If, and to the extent, we obtain additional funding through sales of securities, any previous investment in us will be diluted, and dilution can be particularly substantial when the price of our common stock is low. Moreover, capital markets have experienced a period of instability recently and this instability may make it harder for us to raise capital within the time periods needed or on terms we consider acceptable, if at all. In the current economic environment, our need for additional capital and limited capital resources may force us to accept financing terms that could be significantly more dilutive than if we were raising capital when the capital markets were more stable.

#### Negative conditions in the global credit markets may impair the liquidity of a portion of our investment portfolio.

Our investment securities consist primarily of government-asset-backed securities, obligations of government agencies and money market funds. As of December 31, 2007, our short-term investments included \$28.0 million of AAA rated asset-backed securities (student loan auction rate securities) issued primarily by state governments. Subsequent to December 31, 2007, we sold \$18.0 million of these asset-backed auction rate securities at par value.

The recent negative conditions in the global credit markets have prevented some investors from liquidating their holdings, including their holdings of student loan auction rate securities. As of March 6, 2008, there was insufficient demand at auction for three of our AAA rated U.S. government-backed student loan auction rate securities, representing approximately \$6.0 million of the remaining \$10.0 million we currently hold in asset-backed auction rate securities. As a result of the insufficient demand, these three securities are currently not liquid and unless a future auction (which occurs approximately every 28 days) for these investments is successful, we could be required to hold them until they are redeemed by the issuer or to maturity, which ranges between 20-30 years.

We may experience a similar situation with our other remaining asset-backed student loan auction rate security, which comes up for auction on March 24, 2008. In the event we need to access the funds that are in an illiquid state, we will not be able to do so without a loss of principal, until a future auction on these investments is successful, the securities are redeemed by the issuer or they mature. At this time, management has not obtained sufficient evidence to conclude that these investments are impaired or that they will not be settled in the short-term, although the market for these investments is presently uncertain. If the credit ratings of the security issuers deteriorate and any decline in market value is determined to be other-than-temporary, we would be required to adjust the carrying value of the investment through an impairment charge.

Our independent registered public accounting firm has issued an unqualified opinion with an explanatory paragraph, to the effect that there is substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has issued an unqualified opinion with an explanatory paragraph, to the effect that there is substantial doubt about our ability to continue as a going concern. This unqualified opinion with an explanatory paragraph could have a material adverse effect on our business, financial condition, results of operations and cash flows. See "Liquidity and Capital Resources" in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

We have no committed sources of capital and do not know whether additional financing will be available when needed on terms that are acceptable, if at all. Our current lack of resources is exacerbated by our inability to liquidate holdings of certain student loan auction rate securities. The addition of this going concern statement from our independent registered public accounting firm may discourage some investors from purchasing our stock or providing alternative capital financing. The failure to satisfy our capital requirements will adversely affect our business, financial condition, results of operations and prospects.

Unless we raise additional funds, either through the sale of equity securities or one or more collaborative arrangements, we will need to halt the Phase 3 ASPEN study and significantly reduce our workforce and our operating expenses. If we do not take these actions, we will not have sufficient funds to continue operations. Even if we take these actions, they may be insufficient, particulary if our costs are higher than projected or unforeseen expenses arise. Halting our Phase 3 ASPEN study or significantly reducing our workforce or operating expenses will adversely affect our business and prospects.

In order to complete our current Phase 3 ASPEN study, we will need to accrue a sufficient number of renal flares by enrolling a sufficient number of patients who meet the trial criteria. If we are unable to successfully complete the trial, our business will be adversely affected and it may be difficult or impossible for us to continue to operate.

The current Phase 3 ASPEN study is an event-driven trial requiring us to accrue a specified number of renal flares to complete the study. We currently target enrolling at least 740 patients to achieve the required number of renal flares. We may need to enroll more patients in order to reach the required number of renal flares. We may have

difficulty enrolling patients because, among other matters, there are specific limitations on the medications that a patient may be taking upon entry into the trial and intense competition for available lupus patients. If we are unable to accrue a sufficient number of renal flares or to timely enroll a sufficient number of patients, we will not be able to successfully complete the current Phase 3 ASPEN study. As a result, it may be difficult or impossible for us to continue to operate.

Results from our clinical trials may not be sufficient to obtain regulatory approvals to market Riquent or our other drug candidates in the United States or other countries on a timely basis, if at all.

Our drug candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. In order to sell any product that is under development, we must first receive regulatory approval. To obtain regulatory approval, we must conduct clinical trials and toxicology studies that demonstrate that our drug candidates are safe and effective. The process of obtaining FDA and foreign regulatory approvals is costly, time consuming, uncertain and subject to unanticipated delays.

The FDA and foreign regulatory authorities have substantial discretion in the approval process and may not agree that we have demonstrated that Riquent is safe and effective. If Riquent is ultimately not found to be safe and effective, we would be unable to obtain regulatory approval to manufacture, market and sell Riquent. Although we have received an approvable letter from the FDA, the analysis of the data from our previous Phase 3 trial of Riquent showed that the trial did not reach statistical significance with respect to its primary endpoint, time to renal flare, or with respect to its secondary endpoint, time to treatment with high-dose corticosteroids or cyclophosphamide. In a preliminary assessment of the MAA submitted in March 2006, the EMEA reviewers indicated that additional clinical data would be needed prior to potential approval. Based on our review of the EMEA assessment, we believe that the current Phase 3 ASPEN study should provide the necessary data; however, since the data would not be available within the timeframe that the EMEA regulations allow for review of the Riquent application we submitted, we withdrew the application. We plan to refile the MAA after the completion of the current Phase 3 ASPEN study, if it is successful. We can provide no assurances that the FDA or foreign regulatory authorities will ultimately approve Riquent or, if approved, what the indication for Riquent will be.

As designed, our current Phase 3 ASPEN study contains multiple dosing levels. Even if the Phase 3 ASPEN study is successful, the FDA or foreign regulatory authorities may require additional studies to define dosing recommendations before we can obtain approval to market Riquent.

Because substantially all of our resources are currently being devoted to Riquent, our inability to obtain any regulatory approval of Riquent as a result of the current Phase 3 ASPEN study would have a severe negative effect on our business, and, in the future, we may not have the financial resources to continue the development of Riquent or any other potential drug candidates.

We are currently devoting nearly all of our resources to the development and approval of Riquent. Accordingly, our efforts with respect to other drug candidates have significantly diminished.

Future development of our small molecules for the treatment of autoimmune diseases and acute and chronic inflammatory disorders depends on our ability to obtain third-party financing for this program through a joint venture, partnership or other collaborative arrangement. As a result, progress with respect to drug candidates other than Riquent, if any, will be significantly delayed and our success and ability to continue to operate depends on whether we obtain regulatory approval to market Riquent.

#### Current and future clinical trials may be delayed or halted.

Current and future clinical trials of Riquent, trials of drugs related to Riquent, or clinical trials of other drug candidates may be delayed or halted. For example, in 2005, for a period of time we limited patient enrollment in our Phase 3 ASPEN trial in an effort to reduce costs. In addition, our Phase 2/3 clinical trial of Riquent was terminated before planned patient enrollment was completed. Current and future trials may be delayed or halted for various reasons, including:

- we do not have sufficient financial resources;
- supplies of drug product are not sufficient to treat the patients in the studies;
- patients do not enroll in the studies at the rate we expect;
- the products are not effective;
- patients experience negative side effects or other safety concerns are raised during treatment;
- the trials are not conducted in accordance with applicable clinical practices; or
- there is political unrest at foreign clinical sites; or
- there are natural disasters at any of our clinical sites.

If any current or future trials are delayed or halted, we may incur significant additional expenses, and our potential approval of Riquent may be delayed, which could have a severe negative effect on our business.

#### We may be required to design and conduct additional trials for Riquent.

We may be required to design and conduct additional studies to further demonstrate the safety and efficacy of Riquent, either before or after a potential approval, which may result in significant expense and delay. The FDA and foreign regulatory authorities may require new or additional clinical trials because of inconclusive results from current or earlier clinical trials (including the previous Phase 2/3 and Phase 3 trials of Riquent), a possible failure to conduct clinical trials in complete adherence to FDA good clinical practice standards and similar standards of foreign regulatory authorities, the identification of new clinical trial endpoints, or the need for additional data regarding safety or efficacy. It is possible that the FDA or foreign regulatory authorities may not ultimately approve Riquent or our other drug candidates for commercial sale in any jurisdiction, even if we believe future clinical results are positive.

#### We may experience shortages of Riquent for use in our clinical studies.

We may experience shortages of Riquent for use in our clinical studies. We are implementing a commercial scale manufacturing process for Riquent, but we have manufactured only a limited number of lots of Riquent at this commercial scale. In addition, the drug supply needed for our current Phase 3 ASPEN study may require us to manufacture significant quantities of Riquent in a compressed time frame. If we are unable to manufacture Riquent in accordance with applicable FDA good manufacturing practices at this commercial scale, or if we incur production delays our ability to timely complete clinical trials of Riquent will be negatively affected.

If we encounter delays or difficulties in establishing or maintaining relationships with manufacturing or distribution contractors, our ability to timely complete necessary clinical trials and potentially deliver commercial products may be negatively affected.

We may enter into arrangements with contract manufacturing companies to expand our own production capacity in order to meet demand for our products or to attempt to improve manufacturing efficiency. If we choose to contract for manufacturing services, the FDA and comparable foreign regulators would have to approve the contract manufacturers prior to our use, and these contractors would be required to comply with strictly enforced manufacturing standards. We may also enter into agreements with contractors to prepare and distribute our drug candidates for use by patients in clinical trials or commercially. If we encounter delays or difficulties in establishing or maintaining relationships with contractors to produce, package or distribute our drug candidates, if they are unable to meet our needs, if they are not approved by the regulatory authorities, or if they fail to adhere to applicable manufacturing standards, our ability to timely complete necessary clinical trials and to introduce our products into the market would be negatively affected.

Our limited manufacturing capabilities and experience could result in shortages of drugs for future sale, and our revenues and profit margin could be negatively affected.

We have never operated a commercial manufacturing facility and we will be required to manufacture Riquent pursuant to applicable FDA good manufacturing practices. Our inexperience could result in manufacturing delays or interruptions and higher manufacturing costs. This could negatively affect our ability to supply the market on a timely and competitive basis. The sales of our products, if any, and our profit margins may also be negatively affected. In addition, substantial capital investment in the expansion and build-out of our manufacturing facilities and/or the engagement of third party contract manufacturers will be required to enable us to manufacture Riquent, if approved, in sufficient commercial quantities. We have limited manufacturing experience, and we may be unable to successfully transition to commercial production.

## Our suppliers may not be able to provide us with sufficient quantities of materials that we need to manufacture our products.

We rely on outside suppliers to provide us with specialized chemicals and reagents that we use to manufacture our drugs. In order to manufacture Riquent and our other drug candidates in sufficient quantities for our clinical trials and possible commercialization, our suppliers will be required to provide us with an adequate supply of chemicals and reagents. Our ability to obtain these chemicals and reagents is subject to the following risks:

- our suppliers may not be able to increase their own manufacturing capabilities in order to provide us with a sufficient amount of material for our use;
- some of our suppliers may be required to pass FDA inspections or validations or to obtain other regulatory approvals of their manufacturing facilities or processes, and they may be delayed or unable to do so;
- the materials that our suppliers use to manufacture the chemicals and reagents that they provide us may be costly or in short supply; and
- there are a limited number of suppliers that are able to provide us with the chemicals or reagents that we use to manufacture our drugs.

If we are unable to obtain sufficient quantities of chemicals or reagents, our ability to produce products for clinical studies and, therefore, to introduce products into the market on a timely and competitive basis, will be impeded. The subsequent sales of our products, if any, and our profit margins may also be negatively affected.

#### An interruption in the operation of our sole manufacturing facility could disrupt our operations.

We have only one drug manufacturing facility. A significant interruption in the operation of this facility, whether as a result of a natural disaster or other causes, could significantly impair our ability to manufacture drugs for our clinical trials or possible commercialization.

## Retaining our current personnel and recruiting additional personnel will be critical to our success.

We are highly dependent on the principal members of our clinical development, manufacturing and management staff, the loss of whose services may delay the achievement of our research and development objectives. Retaining our current key personnel to perform clinical development, manufacturing, regulatory, and business development activities will be critical to our near term success. We expect that recruiting additional qualified personnel to conduct clinical development, manufacturing, regulatory, and marketing and sales activities will be required to successfully further develop Riquent and any additional drug candidates. Because competition for experienced clinical, manufacturing, regulatory, and marketing and sales personnel among numerous pharmaceutical and biotechnology companies and research and academic institutions is intense, we may not be able to attract and retain these people. If we cannot attract and retain qualified people, our ability to conduct necessary clinical trials, manufacture drug, comply with regulatory requirements, enter into collaborative agreements and develop and sell potential products may be negatively affected because, for instance, the trials may not be conducted properly, or the manufacturing or sales of our products may be delayed. In addition, we rely on consultants and advisors to assist us

in formulating our clinical, manufacturing, regulatory, business development, and marketing and sales strategies. All of our consultants and advisors have outside employment and may have commitments or consulting or advisory contracts with other entities that may limit their ability to contribute to our business.

#### We will need additional funds to support our operations.

Our operations to date have consumed substantial capital resources. Before we can obtain FDA or foreign regulatory approval for Riquent, we will need to successfully complete the current Phase 3 ASPEN study and possibly additional trials. Therefore, we expect to expend substantial amounts of capital resources for additional product development and clinical trials of Riquent. We may also devote substantial additional capital resources to establish commercial-scale manufacturing capabilities and to market and sell potential products. These expenses may be incurred prior to or after any regulatory approvals that we may receive. Even with the net proceeds of approximately \$37.9 million from our common stock offering in April 2007, we will need additional funds to finance our future operations. Our future capital requirements will depend on many factors, including:

- the scope and results of our clinical trials;
- our ability to manufacture sufficient quantities of drug to support clinical trials;
- our ability to obtain regulatory approval for Riquent;
- the time and costs involved in applying for regulatory approvals;
- continued scientific progress in our development programs;
- the size and complexity of our development programs;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- competing technological and market developments;
- our ability to establish and maintain collaborative research and development arrangements;
- our need to establish commercial manufacturing capabilities; and
- our ability to develop effective marketing and sales programs.

We expect to incur substantial losses each year for at least the next several years as we continue our planned clinical trial, manufacturing, regulatory, and development activities. If we receive regulatory approval for Riquent, or any of our other drug candidates, our manufacturing, marketing and sales activities are likely to substantially increase our expenses and our need for additional working capital. In the future, it is possible that we will not be able to obtain additional funds and thus not have adequate resources to support continuation of our business activities.

## Our freedom to operate our business or profit fully from sales of our products may be limited if we enter into collaborative agreements.

We may need to collaborate with other pharmaceutical companies to gain access to their financial, research, drug development, manufacturing, or marketing and sales resources. However, we may not be able to negotiate arrangements with any collaborative partners on favorable terms, if at all. Any collaborative relationships that we enter into may include restrictions on our freedom to operate our business or may limit our revenues from potential products. If a collaborative arrangement is established, the collaborative partner may discontinue funding any particular program or may, either alone or with others, pursue alternative technologies or develop alternative drug candidates for the diseases we are targeting. Competing products, developed by a collaborative partner or to which a collaborative partner has rights, may result in the collaborative partner withdrawing support as to all or a portion of our technology.

Without collaborative arrangements, we must fund our own clinical development, manufacturing, and marketing and sales activities, which accelerates the depletion of our cash and requires us to develop our own manufacturing and marketing and sales capabilities. Therefore, if we are unable to establish and maintain collaborative arrangements and if other sources of cash are not available, we will experience a severe adverse effect on our ability to develop products and, if developed and approved, to manufacture, market and sell them successfully.

Any regulatory approvals that we may obtain for our product candidates may be limited and subsequent issues regarding safety or efficacy could cause us to remove products from the market.

If the FDA or foreign regulatory authorities grant approval of Riquent or any of our other drug candidates, the approval may be limited to specific conditions or patient populations, or limited with respect to its distribution, including to specified facilities or physicians with special training or experience. The imposition of any of these restrictions or other restrictions on the marketing and use of Riquent could adversely affect any future sales of Riquent. Furthermore, even if a drug candidate is approved, it is possible that a subsequent issue regarding its safety or efficacy would require us to remove the drug from the market.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and review, including validation of our manufacturing facilities and processes.

Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, we, and any third-party manufacturers, will be required to adhere to regulations setting forth cGMPs. These regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. Furthermore, we, and any third-party manufacturers, will be subject to periodic inspection by regulatory authorities. These inspections may result in compliance issues that would require the expenditure of significant financial or other resources to address. If we, or any third-party manufacturers that we may engage, fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Although a successful pre-approval inspection was conducted by the FDA in July 2004, we have never operated a commercial manufacturing facility. If we are unable to maintain validated conditions at our manufacturing facilities or fail to successfully validate our manufacturing processes to the satisfaction of the regulatory authorities, they will not approve Riquent for commercial use.

#### The size of the market for our potential products is uncertain.

We estimate that the number of people who suffer from lupus in the United States and Europe is potentially more than 1,000,000 and those with renal impairment, which Riquent is designed to treat, is approximately 300,000. However, there is limited and differing information available regarding the actual size of these patient populations. In addition, it is uncertain whether the results from previous or future clinical trials of Riquent will be observed in broader patient populations, and the number of patients who may benefit from Riquent may be significantly smaller than the estimated patient populations. Furthermore, management of patients with renal disease by specialists other than nephrologists and rheumatologists is likely to reduce our ability to access patients who may benefit from Riquent.

#### Our drugs may not achieve market acceptance.

Even if Riquent or our other drug candidates receive regulatory approval, patients and physicians may not readily or quickly accept our proposed methods of treatment. In order for Riquent or our other drug candidates to be commercially successful, we will need to increase the awareness and acceptance of our drug candidates among physicians, patients and the medical community. Riquent is designed to be administered weekly by intravenous injection. It is possible that providers and patients may resist an intravenously administered therapeutic. It is also possible that physician treatment practices may change and that the use of other drugs, either newly approved or

currently on the market for other conditions, may become widely utilized by clinicians for the treatment of patients with lupus and reduce the potential use of Riquent in this patient population. In addition, if we are unable to manufacture drugs at an acceptable cost, physicians may not readily prescribe drugs that we may manufacture due to cost-benefit considerations when compared to other methods of treatment. If we are unable to achieve market acceptance for approved products, our revenues and potential for profitability will be negatively affected.

#### We lack experience in marketing products for commercial sale.

In order to commercialize any drug candidate approved by the FDA or foreign regulatory authorities, we must either develop marketing and sales programs or enter into marketing arrangements with others. If we cannot do either of these successfully, we will not generate meaningful sales of any products that may be approved. If we develop our own marketing and sales capabilities, we will be required to employ a sales force, establish and staff a customer service department, and create or identify distribution channels for our drugs. We will compete with other companies that have experienced and well-funded marketing and sales operations. In addition, if we establish our own sales and distribution capabilities, we will incur material expenses and may experience delays or have difficulty in gaining market acceptance for our drug candidates. We currently have no marketing arrangements with others. There can be no guarantee that, if we desire to, we will be able to enter into any marketing agreements on favorable terms, if at all, or that any such agreements will result in payments to us. If we enter into co-promotion or other marketing and sales arrangements with other companies, any revenues that we may receive will be dependent on the efforts of others. There can be no guarantee that these efforts will be successful.

#### We may not earn as much revenue as we hope due to possible changes in healthcare reimbursement policies.

The continuing efforts of government and healthcare insurance companies to reduce the costs of healthcare may reduce the amount of revenue that we can generate from sales of future products, if any. For example, in certain foreign markets, pricing and profitability of prescription drugs are subject to government control. In the United States, we expect that there will continue to be a number of federal and state proposals to implement similar government controls. In addition, an increasing emphasis on managed care in the United States will continue to put pressure on drug manufacturers to reduce prices. Price control initiatives could reduce the revenue that we receive for any products we may develop and sell in the future. Moreover, even if Riquent were approved we cannot predict what the dosage requirements or degree of efficacy would be and therefore whether or not healthcare reimbursement policies would enable a sales price that allows us to be profitable.

#### We have a history of losses and may not become profitable.

We have incurred operating losses each year since our inception in 1989 and had an accumulated deficit of approximately \$352.8 million as of December 31, 2007. We expect to incur substantial losses each year for at least the next several years as we conduct clinical trials of our drug candidates, seek regulatory approval and continue our clinical development, manufacturing, and regulatory activities. In addition, assuming we ultimately receive approval from the FDA or foreign regulatory authorities for Riquent or our other drug candidates, we will be required to establish commercial manufacturing capabilities and marketing and sales programs which may result in substantial additional losses. To achieve profitability we must, among other matters, complete the development of our products, obtain all necessary regulatory approvals and establish commercial manufacturing, marketing and sales capabilities. The amount of losses and the time required by us to reach sustained profitability are highly uncertain and we may never achieve profitability. We do not expect to generate revenues from the sale of Riquent, if approved, or our other products, if any, in the near term, and we may never generate product revenues.

Our success in developing and marketing our drug candidates depends significantly on our ability to obtain patent protection for Riquent and any other developed products. In addition, we will need to successfully preserve our trade secrets and operate without infringing on the rights of others.

We depend on patents and other unpatented intellectual property to prevent others from improperly benefiting from products or technologies that we may have developed. We currently own 135 issued patents and have 40 pending patent applications in the United States and in foreign countries. These patents and patent applications cover various technologies and drug candidates, including Riquent. There can be no assurance, however, that any additional patents will be issued, that the scope of any patent protection will be sufficient to

protect us or our technology, or that any current or future issued patent will be held valid if subsequently challenged. We are currently involved in an opposition proceeding in Europe challenging the validity of certain claims in our European patent relating to our antibody-mediated thrombosis drug technology. There is a substantial backlog of biotechnology patent applications at the United States Patent and Trademark Office that may delay the review and issuance of any patents. The patent position of biotechnology firms like ours is highly uncertain and involves complex legal and factual questions, and no consistent policy has emerged regarding the breadth of claims covered in biotechnology patents or the protection afforded by these patents. We intend to continue to file patent applications as believed appropriate for patents covering both our products and processes. There can be no assurance that patents will be issued from any of these applications, or that the scope of any issued patents will protect our technology.

We do not necessarily know if others, including competitors, have patents or patent applications pending that relate to compounds or processes that overlap or compete with our intellectual property or which may affect our freedom to operate. We are aware of certain families of patents and patent applications that contain claims covering subject matter that may affect our ability to develop, manufacture and sell our products in the future. We have conducted investigations into these patent families to determine what impact, if any, the patent families could have on our continued development, manufacture and, if approved by the FDA, sale of our drug candidates, including Riquent. Based on our investigations to date, we currently do not believe that these patent families are likely to impede the advancement of our drug candidates, including Riquent.

However, there can be no assurance that upon our further investigation, these patent families or other patents will not ultimately be found to impact the advancement of our drug candidates, including Riquent. If the United States Patent and Trademark Office or any foreign counterpart issues or has issued patents containing competitive or conflicting claims, and if these claims are valid, the protection provided by our existing patents or any future patents that may be issued could be significantly reduced, and our ability to prevent competitors from developing products or technologies identical or similar to ours could be negatively affected. In addition, there can be no guarantee that we would be able to obtain licenses to these patents on commercially reasonable terms, if at all, or that we would be able to develop or obtain alternative technology. Our failure to obtain a license to a technology or process that may be required to develop or commercialize one or more of our drug candidates may have a material adverse effect on our business. In addition, we may have to incur significant expenses and management time in defending or enforcing our patents.

We also rely on unpatented intellectual property such as trade secrets and improvements, know-how, and continuing technological innovation. While we seek to protect these rights, it is possible that:

- others, including competitors, will develop inventions relevant to our business;
- our confidentiality agreements will be breached, and we may not have, or be successful in obtaining, adequate remedies for such a breach; or
- our trade secrets will otherwise become known or be independently discovered by competitors.

We could incur substantial costs and devote substantial management time in defending suits that others might bring against us for infringement of intellectual property rights or in prosecuting suits that we might bring against others to protect our intellectual property rights.

#### The technology underlying our products is uncertain and unproven.

All of our product development efforts are based on unproven technologies and therapeutic approaches that have not been widely tested or used. To date, no pharmaceutical products that use our technology have been commercialized. The FDA has not determined that we have proven Riquent to be safe and effective in humans, and the technology on which it is based has been used only in our pre-clinical tests and clinical trials. Clinical trials of Riquent may be viewed as a test of our entire approach to developing therapies for antibody-mediated diseases. If Riquent does not work as intended, or if the data from our clinical trials indicates that Riquent is not safe and effective, the applicability of our technology for successfully treating antibody-mediated diseases will be highly uncertain. As a result, there is a significant risk that our therapeutic approaches will not prove to be successful, and there can be no guarantee that our drug discovery technologies will result in any commercially successful products.

Because a number of companies compete with us, many of which have greater resources than we do, and because we face rapid changes in technology in our industry, we cannot be certain that our products will be accepted in the marketplace or capture market share.

Competition from domestic and foreign biotechnology companies, large pharmaceutical companies and other institutions is intense and is expected to increase. A number of companies and institutions are pursuing the development of pharmaceuticals in our targeted areas. Many of these companies are very large, and have financial, technical, sales and distribution and other resources substantially greater than ours. The greater resources of these competitors could enable them to develop competing products more quickly than we are able to, and to market any competing product more quickly or effectively so as to make it extremely difficult for us to develop a share of the market for our products. These competitors also include companies that are conducting clinical trials and pre-clinical studies for the treatment of lupus. Our competitors may develop or obtain regulatory approval for products more rapidly than we do. If the FDA were to approve a drug that is significantly similar in structure to Riquent for the same indication that Riquent is designed to treat, and such drug received marketing exclusivity under the Orphan Drug Act, the FDA may be prevented from approving Riquent. Also, the biotechnology and pharmaceutical industries are subject to rapid changes in technology. Our competitors may develop and market technologies and products that are more effective or less costly than those we are developing, or that would render our technology and proposed products obsolete or noncompetitive.

#### We may not be able to take advantage of the orphan drug designation for Riquent.

In September 2000, the FDA granted us orphan drug designation for Riquent for the treatment of lupus nephritis. The Orphan Drug Act potentially enables us to obtain research funding and tax credits for certain research expenses. In addition, the Orphan Drug Act allows for seven years of exclusive marketing rights to a specific drug for a specific orphan indication. Exclusivity is conferred upon receipt of marketing approval from the FDA to the first sponsor who obtains such approval for a designated drug. The marketing exclusivity prevents FDA approval during the seven-year period of the same drug, as defined in the FDA regulations, from another company for the same orphan indication. Whether we will be able to take advantage of some of the benefits afforded by the orphan drug designation will ultimately be determined by the FDA only after further review of our NDA.

## The use of Riquent or other potential products in clinical trials, as well as the sale of any approved products, may expose us to lawsuits resulting from the use of these products.

The use and possible sale of Riquent or other potential products may expose us to legal liability and negative publicity if we are subject to claims that our products harmed people. These claims might be made directly by patients, pharmaceutical companies, or others. We currently maintain \$10.0 million of product liability insurance for claims arising from the use of our products in clinical trials. However, product liability insurance is becoming increasingly expensive. In addition, in the event of any commercialization of any of our products, we will likely need to obtain additional insurance, which will increase our insurance expenses. There can be no guarantee that we will be able to maintain insurance or that insurance can be acquired at a reasonable cost, in sufficient amounts, or with broad enough coverage to protect us against possible losses. Furthermore, it is possible that our financial resources would be insufficient to satisfy potential product liability or other claims. A successful product liability claim or series of claims brought against us could negatively impact our business and financial condition.

#### We face environmental liabilities related to certain hazardous materials used in our operations.

Due to the nature of our manufacturing processes, we are subject to stringent federal, state and local laws governing the use, handling and disposal of certain materials and wastes. We may have to incur significant costs to comply with environmental regulations if and when our manufacturing increases to commercial volumes. Current or future environmental laws may significantly affect our operations because, for instance, our production process may be required to be altered, thereby increasing our production costs. In our research and manufacturing activities, we use radioactive and other materials that could be hazardous to human health, safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. The risk of accidental injury or contamination from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any resulting damages, and any such liability could exceed our resources. Although we maintain general liability insurance, we do not specifically insure against environmental liabilities.

#### II. RISK FACTORS RELATED SPECIFICALLY TO OUR STOCK.

## The ownership of our common stock is concentrated.

As of February 29, 2008, our three largest stockholders beneficially owned approximately 47% of our currently outstanding shares of common stock. Investors who purchase our common stock may be subject to certain risks due to the concentrated ownership of our common stock. For example, the sale by any of our large stockholders of a significant portion of that stockholder's holdings could have a material adverse effect on the market price of our common stock. In addition, two of these stockholders have the ability, either alone or jointly, to appoint four members of our board of directors. Accordingly, these two stockholders, either directly or indirectly, have the ability to significantly influence the outcome of all matters submitted to a vote of our stockholders.

## Our common stock price is volatile and may decline even if our business is doing well.

The market price of our common stock has been and is likely to continue to be highly volatile. Market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The following factors, among others, can have a significant effect on the market price of our securities:

- limited financial resources;
- our clinical trial results;
- future sales of significant amounts of our common stock by us or our stockholders;
- actions or decisions by the FDA and other comparable agencies;
- announcements of technological innovations or new therapeutic products by us or others;
- developments in patent or other proprietary rights;
- public concern as to the safety of drugs discovered or developed by us or others;
- developments concerning potential agreements with collaborators;
- comments by securities analysts and general market conditions; and
- government regulation, including any legislation that may impact the price of any commercial products that we may seek to sell.

The realization of any of the risks described in these "Risk Factors" could have a negative effect on the market price of our common stock.

## Future sales of our stock by our stockholders could negatively affect the market price of our stock.

Sales of our common stock in the public market, or the perception that such sales could occur, could result in a drop in the market price of our securities. As of February 29, 2008, there were:

- Approximately 39,619,996 shares of common stock that have been issued in registered offerings or were otherwise freely tradable in the public markets.
- Approximately 10,761 shares of common stock eligible for resale in the public market pursuant to SEC Rule 144.

- 4,399,992 shares of common stock underlying warrants which have been registered for resale under a Registration Statement on Form S-3.
- 5,417,904 shares of common stock that may be issued on the exercise of outstanding stock options granted under our various stock option plans at a weighted average exercise price of \$7.83 per share.
- Approximately 417,949 shares of common stock reserved for future issuance pursuant to awards granted under our equity incentive and employee stock purchase plans, which shares are covered by effective registration statements under the Securities Act of 1933, as amended (the "Securities Act").
- Pursuant to a registration statement on Form S-3 filed on December 10, 2002, we registered an aggregate amount of \$125,000,000 of our common stock for issuance from time to time. As of February 29, 2008, there was \$13,917,500 of our common stock available for future issuance under this registration statement, which expires on December 1, 2008.
- Pursuant to a registration statement on Form S-3 filed on August 20, 2007, we registered an aggregate amount of \$77,000,000 of our common stock for issuance from time to time. As of February 29, 2008, no shares of common stock had been issued under this registration statement, which expires on August 23, 2010.

We cannot estimate the number of shares of common stock that may actually be resold in the public market because this will depend on the market price for our common stock, the individual circumstances of the sellers and other factors. We also have a number of stockholders that own significant blocks of our common stock. If these stockholders sell significant portions of their holdings in a relatively short time, for liquidity or other reasons, the market price of our common stock could drop significantly.

Our stock may be removed from listing on the Nasdaq Global Market and may not qualify for listing on any stock exchange, in which case it may be difficult to maintain a market in our stock.

In 2005, we received a notice from the Nasdaq Stock Market that our stock price fell below the required minimum bid price. We have since regained compliance with the minimum bid price rule, but we are required to maintain compliance in order to maintain our listing. In addition to the minimum bid price rule, the Nasdaq Global Market has several other continued listing requirements. Failure to maintain compliance with any Nasdaq listing requirement could cause our stock to be removed from listing on Nasdaq. If this were to happen, we may not be able to secure listing on other exchanges or quotation systems. If our stock is no longer traded on an exchange or quotation system, it may be difficult for our stockholders to sell the shares that they own. This would have a negative effect on the price and liquidity of our stock.

Failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

Section 404 of the Sarbanes-Oxley Act requires us to evaluate annually the effectiveness of our internal controls over financial reporting as of the end of each fiscal year beginning in 2004 and to include a management report assessing the effectiveness of our internal control over financial reporting in all future annual reports beginning with the annual report on Form 10-K for the fiscal year ended December 31, 2004. Section 404 also requires our independent registered public accounting firm to report on our internal control over financial reporting. We evaluated our internal control over financial reporting as of December 31, 2007 in order to comply with Section 404 and concluded that our disclosure controls and procedures were effective as of such date. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we cannot provide any assurances that we will be able to conclude in the future that we have effective internal control over financial reporting in accordance with Section 404. If we fail to achieve and maintain a system of effective internal control over financial reporting, it could have a material adverse effect on our business and stock price.

# Anti-takeover devices may prevent changes in our board of directors and management.

We have in place several anti-takeover devices, including a stockholder rights plan, which may have the effect of delaying or preventing changes in our management or deterring third parties from seeking to acquire significant positions in our common stock. For example, one anti-takeover device provides for a board of directors that is separated into three classes, with their terms in office staggered over three year periods. This has the effect of delaying a change in control of our board of directors without the cooperation of the incumbent board. In addition, our bylaws require stockholders to give us written notice of any proposal or director nomination within a specified period of time prior to the annual stockholder meeting, establish certain qualifications for a person to be elected or appointed to the board of directors during the pendency of certain business combination transactions, and do not allow stockholders to call a special meeting of stockholders.

We may also issue shares of preferred stock without further stockholder approval and upon terms that our board of directors may determine in the future. The issuance of preferred stock could have the effect of making it more difficult for a third party to acquire a majority of our outstanding stock, and the holders of such preferred stock could have voting, dividend, liquidation and other rights superior to those of holders of our common stock.

#### Item 1B. Unresolved Staff Comments.

None.

# Item 2. Properties.

We lease two adjacent buildings in San Diego, California covering a total of approximately 54,000 square feet. One building contains our research and development laboratories and clinical manufacturing facilities and the other contains our corporate offices and warehouse. Both building leases expire in July 2009. Each lease is subject to an escalation clause that provides for annual rent increases. We believe that these facilities will be adequate to meet our needs for the near term. Over the longer term, management believes that additional space can be secured at commercially reasonable rates.

#### Item 3. Legal Proceedings.

We are not currently a party to any legal proceedings.

#### Item 4. Submission of Matters to a Vote of Security Holders.

None.

#### PART II

# Item 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

#### **Information About Our Common Stock**

Our common stock trades on the Nasdaq Global Market under the symbol "LJPC." Set forth below are the high and low sales prices for our common stock for each full quarterly period within the two most recent fiscal years.

		Pri	ces	
77 P 1 1 P 1 A 1 A 1 A 1 A 1 A 1 A 1 A 1 A	_1	<u>High</u>	_[	<u>.ow</u>
Year Ended December 31, 2007				
First Quarter	\$	8.57	\$	2.80
Second Quarter	Ψ	8.68	-	4.35
Third Quarter		5.59		3.15
Third Quarter Fourth Quarter		4.50		3.15
Year Ended December 31, 2006				
First Quarter	\$	5,65	\$	3.28
Second Ouarter	-	4.95		3.47
Third Ouarter		4.10		3.50
Fourth Quarter		3.79		2.77

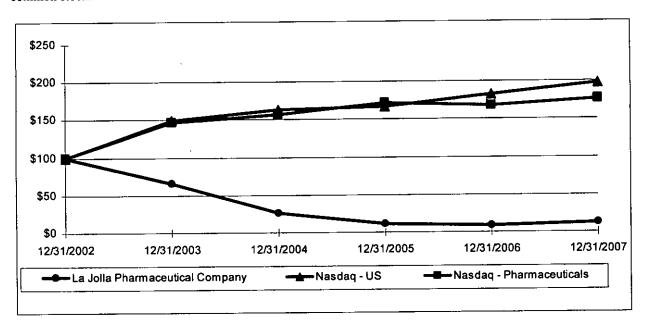
We have never paid dividends on our common stock and we do not anticipate paying dividends in the foreseeable future. The number of record holders of our common stock as of February 29, 2008 was approximately 207.

# Information About Our Equity Compensation Plans

Information regarding our equity compensation plans is incorporated by reference in Item 12 of Part III of this annual report of Form 10-K.

# Stock Performance Graph

The following graph compares the cumulative total stockholder return on our common stock for the five years ended December 31, 2007 with the Center for Research in Securities Prices ("CRSP") Total Return Index for the Nasdaq Global Market (U.S. Companies) and the CRSP Total Return Index for Nasdaq Pharmaceutical Stocks (comprising all companies listed in the Nasdaq Global Market under SIC 283). The graph assumes that \$100 was invested on December 31, 2002 in our common stock and each index and that all dividends were reinvested. No cash dividends have been declared on our common stock. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.



	12/31/2002	12/31/2003	12/31/2004	12/31/2005	12/31/2006	12/31/2007
La Jolla Pharmaceutical Company*	\$100	\$ 65.54	\$ 25.69	\$ 11.38	\$ 9.32	\$ 12.06
Nasdaq — US	\$100	\$149.52	\$162.72	\$166.18	\$ 182.57	\$ 197.98
Nasdag — Pharmaceuticals	\$100	\$ 146.59	\$156.13	\$171.93	\$ 168.29	\$ 176.97

<sup>\*</sup> La Jolla Pharmaceutical Company stock prices have been adjusted to reflect the one-for-five reverse stock split effective December 21, 2005.

# Item 6. Selected Financial Data.

The following Selected Financial Data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 beginning at page 29 and the consolidated financial statements of the Company and related notes thereto beginning at page F-2 of this report.

Years Ended December 31.									
	2007	_	2006	_	2005		2004		2003
(In thousands, except per share amounts)						ımounts)			
\$	46,635	\$	32,938	\$	22,598	\$	33,169	\$	32,385
								•	6,908
_				-				_	(39,293)
	(33,093)		(42,223)		(20,003)		(+0,/5/)		(37,273)
	(82)		(46)		(116)		(100)		(210)
					, ,		, ,		` ,
	2,099		2,820		/30		363		665
dr.	(52.07()	•	(20.445)	•	(27.2(2)	•	(40.544)	•	(20.020)
<u> </u>	(33,076)	3	(39,445)	<u> </u>	(2/,303)	2	(40,544)	<u> </u>	(38,838)
_	/4 .4.	_		_	<b></b> \	_		_	
<u>\$</u>	(1.40)	\$	(1.21)	\$	(1.77)	\$	(3.40)	\$	(4.24)
	37,818		32,588		15,446		11,941		9,161
S	. 29 881	\$	37 673	\$	70 124	\$	17.539	\$	28,914
Č	. *					-	•	-	41,944
Ψ	77,703	Ψ	77,525	Φ	00,920	Ψ	33,020	Ф	71,277
•	200	ው	107	ď	1.42		717	d.	1 244
				-		-		•	1,341
\$	33,521	\$	43,089	\$	77,130	\$	26,001	\$	36,427
	- \$ \$	\$ 46,635 9,058 (55,693) (82) 2,699 \$ (53,076) \$ (1.40) 37,818 \$ 29,881 \$ 44,405 \$ 388	\$ 46,635 \$ 9,058 (55,693) (82) 2,699 \$ (53,076) \$ \$ (1.40) \$ \$ 37,818 \$ \$ 44,405 \$ \$ 388 \$	\$ 46,635 \$ 32,938 9,058 9,287 (55,693) (42,225)  (82) (46) 2,699 2,826  \$ (53,076) \$ (39,445)  \$ (1.40) \$ (1.21)  37,818 32,588  \$ 29,881 \$ 37,673 \$ 44,405 \$ 49,525  \$ 388 \$ 196	\$ 46,635 \$ 32,938 \$ 9,058 9,287 (55,693) (42,225)  (82) (46) 2,699 2,826  \$ (53,076) \$ (39,445) \$ \$ (1.40) \$ (1.21) \$ \$ 37,818 32,588  \$ 29,881 \$ 37,673 \$ \$ 44,405 \$ 49,525 \$ \$ \$	2007       2006 (In thousands, except per shade)         \$ 46,635       \$ 32,938       \$ 22,598         9,058       9,287       5,405         (55,693)       (42,225)       (28,003)         (82)       (46)       (116)         2,699       2,826       756         \$ (53,076)       \$ (39,445)       \$ (27,363)         \$ (1.40)       \$ (1.21)       \$ (1.77)         37,818       32,588       15,446         \$ 29,881       \$ 37,673       \$ 70,124         \$ 44,405       \$ 49,525       \$ 80,928         \$ 388       \$ 196       \$ 142	2007     2006     2005       (In thousands, except per share at the state at t	2007       2006 (In thousands, except per share amounts)         \$ 46,635 (In thousands, except per share amounts)         \$ 22,598 (In thousands, except per share amounts)         \$ (1.40) (In thousands, except per share amounts)	2007       2006 (In thousands, except per share amounts)         \$ 46,635 (In thousands, except per share amounts)         \$ 9,058 (In thousands, except per share amounts)         \$ 9,058 (In thousands, except per share amounts)         \$ 22,598 (In thousands, except per share amounts)         \$ (1.40) (In thousands, except per share amounts)

<sup>(1)</sup> Shares have been adjusted to reflect the one-for-five reverse stock split effective December 21, 2005.

# Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

#### Introduction

Management's discussion and analysis of financial condition and results of operations is provided as a supplement to the accompanying consolidated financial statements and footnotes to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. Our discussion is organized as follows:

- Recent developments. This section provides a general description of recent events and significant transactions that we believe are important in understanding our financial condition and results of operations.
- Overview. This section provides a general description of our business and operating history.
- Critical accounting policies and estimates. This section contains a discussion of the accounting policies
  that we believe are important to our financial condition and results of operations and that require significant
  judgment and estimates on the part of management in their application. In addition, all of our significant
  accounting policies, including the critical accounting policies and estimates, are summarized in Note 1 to
  the accompanying consolidated financial statements.
- Results of operations. This section provides an analysis of our results of operations presented in the accompanying consolidated statements of operations by comparing the results for the year ended December 31, 2007 to the results for the year ended December 31, 2006 and comparing the results for the year ended December 31, 2006 to the results for the year ended December 31, 2005.
- Liquidity and capital resources. This section provides an analysis of our cash flows and a discussion of our outstanding debt and commitments, both firm and contingent, that existed as of December 31, 2007.
   Included in the discussion of outstanding debt is a discussion of our financial capacity to fund our future commitments and a discussion of other financing arrangements.

# **Recent Developments**

2008

On February 11, 2008, we announced that we had made significant progress in our current Phase 3 ASPEN study in that we had enrolled 607 patients and 130 clinical trial sites were open to enroll patients in 23 countries. In addition, we also announced that our current enrollment target of at least 740 patients was expected to be completed around the end of the second quarter of 2008.

2007

On February 1, 2007, we announced that we had made continued progress in enrolling patients in our Phase 3 ASPEN study in that we had enrolled 202 patients in the study and 74 clinical trial sites were open to enroll patients, including newly added sites in Europe and Mexico. In addition, we also announced that following discussions with the FDA, we implemented several enhancements to further strengthen the Phase 3 ASPEN study, which remains under Special Protocol Assessment. These enhancements included a focus on higher doses and increase in sample size.

On March 8 and March 20, 2007, we announced positive interim antibody results from our current Phase 3 ASPEN study. Analyses of interim antibody data indicated that patients treated with 900 mg or 300 mg per week doses of Riquent had greater reductions in antibodies to dsDNA than patients treated with 100 mg per week or placebo. The results showed a significant dose response when comparing all Riquent-treated patients to placebotreated patients (p = 0.0001), and each Riquent dose group to the placebo dose group (p < 0.0032 for 100 mg, p < 0.0001 for 300 mg and 900 mg).

On March 29, 2007, we announced the pricing of an underwritten public offering of 5,800,000 shares of our common stock at \$6.00 per share. In connection with this offering, we granted the underwriters an option to purchase up to an additional 870,000 shares to cover over-allotments. On April 10, 2007, we announced that we had completed the public offering for total net proceeds of approximately \$37.9 million, including the proceeds from the over-allotment shares.

On April 26, 2007, we announced that composition of matter patents covering Riquent have issued in both Europe and in the People's Republic of China. If the full five years of patent term extension under a Supplemental Protection Certificate is granted, the term of the European patent would extend to December 2, 2018. The Chinese patent will be in effect until September 8, 2014.

On May 10, 2007, we announced that Niv E. Caviar had joined the Company as Executive Vice President, Chief Business Officer and Chief Financial Officer.

On May 24, 2007, we announced that we had presented three papers related to Riquent at the 8th International Congress on SLE. The first presentation reviewed recently announced safety and interim antibody data from the current Phase 3 ASPEN study which highlighted the statistically significant dose response observed between the 100 mg, 300 mg and 900 mg doses of Riquent compared with placebo (p=0.0001). The second presentation reviewed the safety and drug levels of Riquent at doses up to 2,400 mg in healthy volunteers and the third, cardiovascular safety in healthy volunteers.

#### Overview

Since our inception in May 1989, we have devoted substantially all of our resources to the research and development of technology and potential drugs to treat antibody-mediated diseases. We have never generated any revenue from product sales and have relied on public and private offerings of securities, revenue from collaborative agreements, equipment financings and interest income on invested cash balances for our working capital. We expect that our research and development expenses will increase significantly in the future. For example, we are conducting and expanding a Phase 3 clinical trial of Riquent which the FDA has indicated appears to satisfy the requirement that we conduct an additional randomized, double-blind study. This study is an event drive trial requiring us to accrue a specified number of renal flares to complete the study. We currently target enrolling at least 740 patients to achieve the required number of renal flares and the trial could take several years to complete. Therefore, we expect to expend substantial amounts of capital resources for the clinical development and manufacturing of Riquent. We may also devote substantial additional capital resources to establish commercial-scale manufacturing capabilities and to market and sell potential products. These expenses may be incurred prior to or after any regulatory approvals that we may receive. In addition, our research and development expenses may increase if we initiate any additional clinical studies of Riquent or if we increase our activities related to any additional drug candidates. We will need additional funds to finance our future operations. Our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and the financial information included in this report are not necessarily indicative of our future operating results or financial condition.

We expect our net loss to fluctuate from quarter to quarter as a result of the timing of expenses incurred and the revenues earned from any potential collaborative arrangements that we may establish. Some of these fluctuations may be significant. As of December 31, 2007, our accumulated deficit was approximately \$352.8 million.

Our business is subject to significant risks, including, but not limited to, the need for additional financing or a collaborative partner to continue our clinical activities and continue to operate, the risks inherent in research and development efforts, including clinical trials, the lengthy, expensive and uncertain process of seeking regulatory approvals, uncertainties associated with both obtaining and enforcing patents, the potential enforcement of the patent rights of others against us, uncertainties regarding government reforms regarding product pricing and reimbursement levels, technological change, competition, manufacturing uncertainties, our lack of marketing experience, the uncertainty of receiving future revenue from product sales or other sources such as collaborative relationships, and the uncertainty of future profitability. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons, including the possibilities that the products will be ineffective or unsafe during clinical trials, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by the proprietary rights of third parties or competing products.

#### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to patent costs and clinical/regulatory expenses. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

We believe the following critical accounting policies involve significant judgments and estimates used in the preparation of our consolidated financial statements (see also Note 1 to our consolidated financial statements included in Part IV).

# Impairment and useful lives of long-lived assets

We regularly review our long-lived assets for impairment. Our long-lived assets include costs incurred to file our patent applications. We evaluate the recoverability of long-lived assets by measuring the carrying amount of the assets against the estimated undiscounted future cash flows associated with them. At the time such evaluations indicate that the future undiscounted cash flows of certain long-lived assets are not sufficient to recover the carrying value of such assets, the assets are adjusted to their fair values. The estimation of the undiscounted future cash flows associated with long-lived assets requires judgment and assumptions that could differ materially from the actual results. While we believe our current and historical operating and cash flow losses are indicators of impairment, we believe the future cash flows to be received from the long-lived assets will exceed the assets' carrying value. There were no impairment losses recognized for the year ended December 31, 2007. We have recognized approximately \$0.1 million in impairment losses for each of the years ended December 31, 2006 and December 31, 2005.

Costs related to successful patent applications are amortized using the straight-line method over the lesser of the remaining useful life of the related technology or the remaining patent life, commencing on the date the patent is issued. Legal costs and expenses incurred in connection with pending patent applications have been capitalized. We expense all costs related to abandoned patent applications. If we elect to abandon any of our currently issued or unissued patents, the related expense could be material to our results of operations for the period of abandonment. The estimation of useful lives for long-lived assets requires judgment and assumptions that could differ materially from the actual results. In addition, our results of operations could be materially impacted if we begin amortizing the costs related to unissued patents.

#### Accrued clinical/regulatory expenses

We review and accrue clinical trial and regulatory-related expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, sites activated and other events. We follow this method because reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. Accrued clinical/regulatory costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development costs; however a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

#### Share-Based Compensation

We adopted Statement of Financial Accounting Standard ("SFAS") No. 123R, Share-Based Payments ("SFAS 123R") using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our 2006 fiscal year. Our Consolidated Statement of Operations as of and for the years ended December 31, 2007 and 2006 reflect the impact of SFAS 123R. In accordance with the modified prospective transition method, our Consolidated Statements of Operations for prior periods have not been

restated to reflect, and do not include, the impact of SFAS 123R. Share-based compensation expense recognized under SFAS 123R for the years ended December 31, 2007 and December 31, 2006 was approximately \$4.8 million and \$5.0 million, respectively. As of December 31, 2007, there was approximately \$6.9 million of total unrecognized compensation cost related to non-vested share-based payment awards granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. We currently expect to recognize the remaining unrecognized compensation cost over a weighted-average period of 1.1 years. Additional share-based compensation expense for any new share-based payment awards granted after December 31, 2007 under all equity compensation plans cannot be predicted at this time because it will depend on, among other matters, the amounts of share-based payment awards granted in the future.

Prior to January 1, 2006, we had adopted the disclosure-only provision of SFAS No. 123, Accounting and Disclosure of Stock-Based Compensation ("SFAS 123"). Accordingly, we had not previously recognized compensation expense, except for compensation expense related to stock options granted to consultants and restricted stock granted to certain members of management. Had we recognized compensation expense in accordance with SFAS 123 for the year ended December 31, 2005, our net loss would have increased by approximately \$3.8 million or \$0.25 per basic and diluted share.

Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions and are fully transferable. Because the employee and director stock options granted by us have characteristics that are significantly different from traded options, and because changes in the subjective assumptions can materially affect the estimated value, in our opinion the existing valuation models may not provide an accurate measure of the fair value of the employee and director stock options granted by us. Although the fair value of the employee and director stock options granted by us is determined in accordance with SFAS 123R using an option-pricing model, that value may not be indicative of the fair value observed in a willing-buyer/willing-seller market transaction.

#### **New Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, Fair Value Measurements ("SFAS 157"). SFAS 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice resulting from the application of SFAS 157 relate to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We are currently assessing the impact of SFAS 157 on our consolidated results of operations and financial condition.

On January 1, 2007, we adopted FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes ("FIN 48"), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. FIN 48 prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken in a tax return. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures and transition. See Note 8 to the consolidated financial statements for discussion on the impact of FIN 48 to our consolidated results of operations and financial condition.

In February 2007, FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities – Including an amendment of FASB Statement No. 115 ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We are currently assessing the impact of SFAS 159 on our consolidated results of operations and financial condition.

In June 2007, FASB ratified the consensus reached by the Emerging Issues Task Force ("EITF") on EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities ("ETF 07-3"). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The adoption of EITF 07-3 is not expected to have a material effect on our consolidated financial statements.

#### **Results of Operations**

#### Years Ended December 31, 2007, 2006 and 2005

Research and Development Expense. Our research and development expense increased to \$46.6 million for the year ended December 31, 2007 from \$32.9 million in 2006. The increase in research and development expenses in 2007 from 2006 resulted primarily from an increase in Riquent-related drug production and clinical trial expenses of approximately \$16.0 million. This increase was partially offset by a decrease of approximately \$3.2 million in expenses in 2007 as compared to 2006 for the development of our SSAO program, as all of our resources are being devoted to the development of Riquent and further development of the SSAO program depends on our ability to enter into a joint venture, partnership or other collaborative arrangement for this program.

Research and development expense of \$46.6 million for the year ended December 31, 2007 consisted of \$46.0 million for lupus research and development related expense and \$0.6 million for SSAO research and development related expense. Total lupus research and development expense consisted primarily of Riquent related clinical trial expenses and clinical drug supply, salaries and other costs related to manufacturing, clinical and research personnel and fees for consulting and professional outside services. Total SSAO research and development expense consisted primarily of salaries and other costs related to research and development personnel, and depreciation expense.

Our research and development expense increased to \$32.9 million for the year ended December 31, 2006 from \$22.6 million in 2005. The increase in research and development expenses in 2006 from 2005 resulted primarily from an increase in Riquent-related drug production and clinical trial expenses of approximately \$8.2 million. In addition, the increase was due to share-based compensation expense recorded in connection with the adoption of SFAS 123R of approximately \$1.8 million and an increase in Riquent-related consulting expenses of approximately \$0.6 million. These increases were partially offset by a decrease in termination benefits, mainly relating to severance, of approximately \$1.0 million that was recorded in 2005 in connection with the termination of 44 research and development personnel, and the savings in salaries and related expenses as a result of this reduction in personnel.

We expect that our research and development expense will increase significantly in the future. For example, we are conducting and expanding a clinical trial of Riquent that the FDA has indicated appears to satisfy the requirement that we conduct an additional randomized, double-blind study. The study is currently targeted to enroll at least 740 patients and could take several years to complete. As patient enrollment expands in our Phase 3 ASPEN study, our expenses for the manufacturing of Riquent will also increase. Additionally, our research and development expenses may increase significantly if we initiate any additional clinical studies of Riquent or if we increase our activities related to the development of additional drug candidates.

General and Administrative Expense. Our general and administrative expense decreased to \$9.1 million for the year ended December 31, 2007 from \$9.3 million in 2006. The decrease in general and administrative expense in 2007 from 2006 resulted primarily from a decrease in termination benefits, which for 2006 were mainly severance of approximately \$0.9 million and compensation expense of approximately \$0.8 million for accelerated stock option vesting related to the former Chairman and Chief Executive Officer's departure in the first quarter of 2006. This decrease was partially offset by the increase in the write-off of selected patent applications for technologies not related to Riquent or our small molecule SSAO inhibitors program of approximately \$0.7 million, an increase in share-based compensation expense of approximately \$0.5 million for stock options granted in 2006 and 2007 and an increase in consulting expenses for business development and market research of approximately \$0.4 million.

Our general and administrative expense increased to \$9.3 million for the year ended December 31, 2006 from \$5.4 million in 2005. The increase in general and administrative expense in 2006 from 2005 resulted primarily from share-based compensation expense recorded in connection with the adoption of SFAS 123R of approximately \$3.2 million. The increase was also due to the expense recorded in the first quarter of 2006 for severance paid to the former Chairman and Chief Executive Officer of approximately \$0.9 million and an increase in general corporate consulting and professional outside services of approximately \$0.6 million. These increases were partially offset by a decrease in termination benefits, mainly relating to severance, of approximately \$0.5 million that was recorded in 2005 in connection with the termination of 16 general and administrative personnel, and the savings in salaries and related expenses as a result of this reduction in personnel.

General and administrative expense will increase in the future to support our ongoing clinical trials as patient enrollment and the manufacturing of Riquent increases. Additionally, general and administrative expense may increase in the future if there is an increase in research and development or commercialization activities.

Interest Income and Expense. Our interest income was comparable for the years ended December 31, 2007 and December 31, 2006. Our interest income increased to \$2.8 million for the year ended December 31, 2006 from \$0.8 million for 2005 due to higher average balances of cash and short-term investments and higher average interest rates on our investments as compared to 2005. Interest expense was comparable for the years ended December 31, 2007, 2006 and 2005.

Net Operating Loss and Research Tax Credit Carryforwards. At December 31, 2007, we had federal and California income tax net operating loss carryforwards of approximately \$316.1 million and \$169.4 million, respectively. The difference between the federal and California tax loss carryforwards is primarily attributable to the capitalization of research and development expenses for California income tax purposes. In addition, we had federal and California research and development tax credit carryforwards of \$15.3 million and \$8.9 million, respectively. The federal net operating loss and research tax credit carryforwards will begin to expire in 2008 unless previously utilized. The California net operating loss carryforwards will begin to expire in 2009 unless previously utilized. The California research and development credit carryforwards will carry forward indefinitely until utilized.

We are currently undergoing a Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Until this analysis has been completed we have removed the deferred tax assets for net operating losses of \$120.4 million and research and development credits of \$21.1 million generated through 2007 from our deferred tax asset schedule and have recorded a corresponding decrease to our valuation allowance. When this analysis is finalized, we plan to update unrecognized tax benefits under FIN No. 48. We expect the Section 382 analysis to be completed within the next twelve months. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

#### Liquidity and Capital Resources

From inception through December 31, 2007, we have incurred a cumulative net loss of approximately \$352.8 million and have financed our operations through public and private offerings of securities, revenues from collaborative agreements, equipment financings and interest income on invested cash balances. From inception through December 31, 2007, we had raised approximately \$375.6 million in net proceeds from sales of equity securities.

As of December 31, 2007, we had \$39.4 million in cash, cash equivalents and short-term investments, as compared to \$42.9 million as of December 31, 2006. Our working capital as of December 31, 2007 was \$29.9 million, as compared to \$37.7 million as of December 31, 2006. The decrease in cash, cash equivalents and shortterm investments resulted from the use of our financial resources to fund our clinical trial and manufacturing activities, research and development efforts, and for other general corporate purposes, offset by the net proceeds of \$37.9 million from the sale of 6.7 million shares of our common stock in April 2007. We invest our cash primarily in AAA rated government-asset-backed securities, obligations of government agencies, and money market funds. As of December 31, 2007, all of our investments are classified as available-for-sale securities because we expect to sell them in order to support our current operations regardless of their maturity dates. As of December 31, 2007, available-for-sale securities and cash equivalents of \$9.0 million have stated maturity dates of one year or less and \$28.0 million have maturity dates after one year. Securities that have a maturity date greater than one year have their interest rate reset periodically within time periods not exceeding 92 days. Subsequent to December 31, 2007, we sold \$18.0 million of our asset-backed auction rate securities at par value. As of March 6, 2008, there was insufficient demand at auction for three of our AAA rated U.S. government-backed student loan auction rate securities, representing approximately \$6.0 million of the remaining \$10.0 million we currently hold in asset-backed auction rate securities. As a result of the insufficient demand, these three securities are currently not liquid and unless a future auction (which occurs approximately every 28 days) for these investments is successful, we could be required to hold them until they are redeemed by the issuer or to maturity, which ranges between 20-30 years. We may experience a similar situation with our other remaining asset-backed student loan auction rate security of \$4.0 million, which comes up for auction on March 24, 2008. In the event we need to access the funds that are in an illiquid state, we will not be able to do so without a loss of principal, until a future auction on these investments is successful, the securities are redeemed by the issuer or they mature. At this time, management has not obtained sufficient evidence to conclude that these investments are impaired or that they will not be settled in the short-term, although the market for these investments is presently uncertain. If the credit ratings of the security issuers deteriorate and any decline in market value is determined to be other-than-temporary, we would be required to adjust the carrying value of the investment through an impairment charge. See note 9 to our consolidated financial statements for further information.

As of December 31, 2007, approximately \$0.9 million of equipment (\$0.6 million net of depreciation) is financed under notes payable and capital lease obligations. In December 2006, we entered into a credit facility to fund equipment purchases up to \$1.8 million until the end of the second quarter of 2008. In addition, we lease our office and laboratory facilities and certain equipment under operating leases. We have also entered into non-cancelable purchase commitments for an aggregate of \$1.4 million with third-party manufacturers of materials to be used in the production of Riquent. We intend to use our current financial resources to fund our obligations under these purchase commitments. In the future, we may increase our investments in property and equipment if we expand our manufacturing and development facilities and capabilities.

The following table summarizes our contractual obligations as of December 31, 2007. Long-term debt and capital lease obligations include interest.

Payment due by period (in the								usanusj			
Less than									ore than		
Total		1 Year		1 Year 1-3 Y		Years 3-5 Year		5	Years		
\$	568	\$	179	\$	389	\$		\$	_		
	1,424		830		594		_				
	69		15		42		12				
	1,412		1,412		_						
\$	3,473	\$	2,436	\$	1,025	\$	12_	\$			
	\$	\$ 568 1,424 69	Total   1   568   \$   1,424   69	Total Less than 1 Year \$ 568 \$ 179 1,424 830 69 15 1,412 1,412	Total 1 Year 1- \$ 568 \$ 179 \$ 1,424 830 69 15 1,412 1,412	Total         Less than 1 Year         1-3 Years           \$ 568         \$ 179         \$ 389           1,424         830         594           69         15         42           1,412         1,412         —	Total         Less than 1 Year         1-3 Years         3-5           \$ 568         \$ 179         \$ 389         \$           1,424         830         594         \$           69         15         42         \$           1,412         1,412         —         *	Total         Less than 1 Year         1-3 Years         3-5 Years           \$ 568         \$ 179         \$ 389         \$ —           1,424         830         594         —           69         15         42         12           1,412         1,412         —         —	Total         1 Year         1-3 Years         3-5 Years         5           \$ 568         \$ 179         \$ 389         \$ —         \$           1,424         830         594         —           69         15         42         12           1,412         1,412         —         —		

Danier and description of the sharehands

We intend to use our financial resources to fund the current clinical studies of Riquent, possible future clinical trials, manufacturing activities, research and development efforts and for working capital and other general corporate purposes. The amounts that we actually spend for each purpose may vary significantly depending on a number of factors, including the results from current and future clinical trials, the continued analysis of the clinical trial data of Riquent, the outcome of our meetings with regulatory authorities, the timing of any regulatory applications and approvals, and technological developments. Expenditures also will depend on any establishment of collaborative arrangements and contract research as well as the availability of other funding or financings.

We will continue to seek capital through any number of means, including by issuing our equity securities and by establishing one or more collaborative arrangements. However, there can be no assurance that additional financing will be available to us on acceptable terms, if at all, and our negotiating position in capital-raising efforts may worsen as we continue to use existing resources or if the development of Riquent is delayed or terminated. There is also no assurance that we will be able to enter into further collaborative relationships. In the future, it is possible that we will not have adequate resources to support continuation of our business activities.

We have no current means of generating cash flow from operations. Our lead drug candidate, Riquent, will not generate revenues, if at all, until it has received regulatory approval and has been successfully manufactured, marketed and sold. This process, if completed, will take a significant amount of time. Our other drug candidates are much less developed than Riquent. There can be no assurance that our product development efforts with respect to Riquent or any other drug candidate will be successfully completed, that required regulatory approvals will be obtained or that any product, if introduced, will be successfully marketed or achieve commercial acceptance.

Accordingly, we must continue to rely on outside sources of financing to meet our capital needs for the foreseeable future.

#### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our consolidated financial condition, changes in our consolidated financial condition, expenses, consolidated results of operations, liquidity, capital expenditures or capital resources.

#### Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We invest our excess cash in interest-bearing investment-grade securities which we sell from time to support our current operations. We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions in any material fashion. We currently do not invest in any securities that are materially and directly affected by foreign currency exchange rates or commodity prices.

All of our investment securities are classified as available-for-sale and are therefore reported on the balance sheet at market value. Our investment securities consist primarily of government-asset-backed securities, obligations of government agencies, and money market funds. As of December 31, 2007, our short-term investments included \$28.0 million of AAA rated student loan auction rate securities issued primarily by state governments. Subsequent to December 31, 2007, we sold \$18.0 million of these asset-backed auction rate securities at par value. Our auction rate securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals through auctions.

The recent conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to the security's maximum rate. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature, which could be many years. If the credit ratings of the security issuers deteriorate and any decline in market value is determined to be other-than-temporary, the carrying value of the investment would be required to be adjusted through an impairment charge.

As of March 6, 2008, there was insufficient demand at auctions for three of our AAA rated U.S. government-backed student loan auction rate securities, representing approximately \$6.0 million of our remaining \$10.0 million auction rate securities then outstanding. As a result of this insufficient demand, these three securities may not be liquid and the interest rates have been reset to the security's maximum rate. We may experience a similar situation with our other remaining asset-backed student loan auction rate security of \$4.0 million, which comes up for auction on March 24, 2008. To date, we have not recognized any realized losses on these securities. See note 9 to our consolidated financial statement for further information.

In the event we need to access the funds that are in an illiquid state, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer. At this time, management has not obtained sufficient evidence to conclude that these investments are impaired or that they will not be settled in the short term, although the market for these investments is presently uncertain. If we are unable to sell these securities in the market or they are not redeemed, this could potentially impact our current business plan as we will need the ability to access these funds in the near future.

Based on our cash, cash equivalents and short-term investments at December 31, 2007, a hypothetical 10% increase or decrease in interest rates would increase or decrease our annual interest income and cash flows by approximately \$0.2 million.

#### Item 8. Financial Statements and Supplementary Data.

The financial statements and supplementary data required by this item are set forth above under the caption "Quarterly Results of Operations" on page F-20 and at the end of this report beginning on page F-2 and is incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

#### Item 9A. Controls and Procedures.

#### (a) Disclosure Controls and Procedures; Changes in Internal Control Over Financial Reporting

Our management, with the participation of our principal executive and principal financial officers, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of December 31, 2007. Based on this evaluation, our principal executive and principal financial officers concluded that our disclosure controls and procedures were effective as of December 31, 2007.

There was no change in our internal control over financial reporting during the quarter ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

# (b) Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework.

Based on our assessment, management concluded that, as of December 31, 2007, our internal control over financial reporting was effective based on those criteria.

The independent registered public accounting firm that audited the consolidated financial statements that are included in this Annual Report on Form 10-K has issued an audit report on our internal control over financial reporting. The report appears below.

#### (c) Report Of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

La Jolla Pharmaceutical Company

We have audited La Jolla Pharmaceutical Company's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). La Jolla Pharmaceutical Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, La Jolla Pharmaceutical Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of La Jolla Pharmaceutical Company as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007 of La Jolla Pharmaceutical Company and our report dated March 17, 2008 expressed an unqualified opinion and an explanatory paragraph thereon.

/s/ Ernst & Young LLP

San Diego, California March 17, 2008

#### Item 9B. Other Information.

None.

#### PART III

#### Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our Definitive Proxy Statement for our 2008 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2007. Such information is incorporated herein by reference.

We have adopted a code of conduct that applies to our Chief Executive Officer, Principal Financial Officer, Principal Accounting Officer, and to all of our other officers, directors, employees and agents. The code of conduct is available at the Corporate Governance section of the Investor Relations page on our website at www.ljpc.com. We intend to disclose future amendments to certain provisions of our code of conduct on the above website within four business days following the date of such amendment or waiver.

#### Item 11. Executive Compensation.

Information required by this item will be contained in our Definitive Proxy Statement for our 2008 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2007. Such information is incorporated herein by reference.

# Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be contained in our Definitive Proxy Statement for our 2008 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2007. Such information is incorporated herein by reference.

# Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be contained in our Definitive Proxy Statement for our 2008 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2007. Such information is incorporated herein by reference.

#### Item 14. Principal Accountant Fees and Services.

Information required by this item will be contained in our Definitive Proxy Statement for our 2008 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2007. Such information is incorporated herein by reference.

#### **PART IV**

# Item 15. Exhibits, Financial Statement Schedules.

- (a) Documents filed as part of this report.
- 1. The following consolidated financial statements of La Jolla Pharmaceutical Company are filed as part of this report under Item 8 Financial Statements and Supplementary Data:

Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets at December 31, 2007 and 2006	F-2
Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005	F-3
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005	F-4
Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005	F-5
Notes to Cansolidated Financial Statements	F-6

#### 2. Financial Statement Schedules.

These schedules are omitted because they are not required, or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

# 3. Exhibits.

The exhibit index attached to this report is incorporated by reference herein.

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

# LA JOLLA PHARMACEUTICAL COMPANY

March 17, 2008

By: /s/ Deirdre Y. Gillespie
Deirdre Y. Gillespie, M.D.
President, Chief Executive Officer and
Assistant Secretary

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Deirdre Y. Gillespie Deirdre Y. Gillespie, M.D	President, Chief Executive Officer and Assistant Secretary (Principal Executive Officer)	March 17, 2008
/s/ Niv E. Caviar Niv E. Caviar	Executive Vice President, Chief Business Officer and Chief Financial Officer (Principal Financial Officer)	March 17, 2008
/s/ Gail A. Sloan Gail A. Sloan	Vice President of Finance and Secretary (Principal Accounting Officer)	March 17, 2008
/s/ Thomas H. Adams Thomas H. Adams, Ph.D.	Director	March 17, 2008
/s/ Robert A. Fildes Robert A. Fildes, Ph.D.	Director	March 17, 2008
/s/ Stephen M. Martin Stephen M. Martin	Director	March 17, 2008
/s/ Nader J. Naini Nader J. Naini	Director	March 17, 2008
/s/ Craig R. Smith Craig R. Smith, M.D.	Director	March 17, 2008
/s/ Martin Sutter Martin Sutter	Director	March 17, 2008
/s/ James N. Topper James N. Topper, M.D., Ph.D.	Director .	March 17, 2008
/s/ Frank E. Young Frank E. Young, M.D., Ph.D.	Director	March 17, 2008

#### Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of La Jolla Pharmaceutical Company

We have audited the accompanying consolidated balance sheets of La Jolla Pharmaceutical Company as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of La Jolla Pharmaceutical Company at December 31, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, La Jolla Pharmaceutical Company changed its method of accounting for Share-Based Payments in accordance with Statement of Financial Accounting Standards No. 123R (revised 2004) effective January 1, 2006.

The accompanying financial statements have been prepared assuming that La Jolla Pharmaceutical Company will continue as a going concern. As more fully described in Note 1, La Jolla Pharmaceutical Company has recurring operating losses, an accumulated deficit of \$352.8 million and working capital of \$29.9 million at December 31, 2007. These factors, among others, as discussed in Note 1 to the consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The 2007 consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), La Jolla Pharmaceutical Company's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 17, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California March 17, 2008

# Consolidated Balance Sheets

(In thousands, except share and par value amounts)

		31,		
		2007		2006
Assets				
Current assets:				
Cash and cash equivalents	\$	4,373	\$	3,829
Short-term investments, available-for-sale		34,986		39,080
Prepaids and other current assets		1,018		1,004
Total current assets		40,377		43,913
Property and equipment, net		1,271		2,333
Patent costs and other assets, net		2,757		3,279
,	\$	44,405	\$	49,525
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	2,203	\$	2,125
Accrued clinical/regulatory expenses		6,282		1,530
Accrued expenses		664		1,137
Accrued payroll and related expenses		1,199		1,265
Current portion of obligations under notes payable		138		183
Current portion of obligations under capital leases		10		
Total current liabilities.		10,496		6,240
		<b>,</b>		.,
Non-current portion of obligations under notes payable		344		196
Non-current portion of obligations under capital leases		44		
Commitments				
Stockholders' equity:				
Preferred stock, \$0.01 par value; 8,000,000 shares authorized, no shares issued or				
outstanding				
Common stock, \$0.01 par value; 225,000,000 shares authorized, 39,629,660 and				
32,692,676 shares issued and outstanding at December 31, 2007 and 2006,				
respectively		396		327
Additional paid-in capital		385,944		342,519
Other comprehensive income		14		
Accumulated deficit		(352,833)		(299,757)
Total stockholders' equity		33,521		43,089
• •	\$	44,405	\$	49,525

# Consolidated Statements of Operations

# (In thousands, except per share amounts)

	Years Ended December 31,					
		2007		2006		2005
Expenses:						
Research and development	\$	46,635	\$	32,938	\$	22,598
General and administrative		9,058		9,287		5,405
Total expenses		55,693		42,225		28,003
Loss from operations		(55,693)		(42,225)		(28,003)
Interest expense		(82)		(46)		(116)
Interest expense		2,699		2,826		756
Net loss	\$	(53,076)	\$	(39,445)	\$	(27,363)
Basic and diluted net loss per share	\$	(1.40)	\$	(1.21)	\$	(1.77)
Shares used in computing basic and diluted net loss per share		37,818		32,588		15,446

# Consolidated Statements of Stockholders' Equity (In thousands) For the Years Ended December 31, 2005, 2006 and 2007

	Common	stock		Additional paid-in	Other comprehensive	Accumulated	Total stockholders'
- -	Shares	Amoun		capital	income (loss)	deficit	equity
Balance at December 31, 2004	12,302	\$ 123	3 S	258,850	\$ (23)	\$(232,949)	\$ 26,001
Issuance of common stock, net	20,050	200		77,955	(25)		78,155
Issuance of common stock under							,
Employee Stock Purchase Plan	95	1	l	287		_	288
Exercise of stock options	3	_	-	6	<del></del>	_	6
Share-based compensation expense	83	1	l	19		_	20
Net loss		_	-			(27,363)	(27,363)
Net unrealized gains on available-for-							
sale securities	_	_	-	_	23	_	23
Comprehensive loss							(27,340)
Balance at December 31, 2005	32,533	325	5	337,117		(260,312)	77,130
Issuance of common stock under							
Employee Stock Purchase Plan	80	1	l	226	_	_	227
Exercise of stock options	56	1	l	125		<del></del>	126
Share-based compensation expense	24	_	-	5,051		<del></del>	5,051
Net loss					_	(39,445)	(39,445)
Balance at December 31, 2006	32,693	327		342,519	<del></del>	(299,757)	43,089
Issuance of common stock, net	6,670	67	7	37,845		_	37,912
Issuance of common stock under				240			261
Employee Stock Purchase Plan	97		l	260	_		261
Exercise of stock options	166		l	499	_	_	500
Share-based compensation expense	4	_	-	4,821		(62.05()	4,821
Net loss	_		-			(53,076)	(53,076)
Net unrealized gains on available-for-							1.4
sale securities	_	_	-	_	14	_	14
Comprehensive loss	20.600			205.044	<u> </u>	0 (0.50, 0.00)	(53,062)
Balance at December 31, 2007	39,630	\$ 396	<u> </u>	385,944	<b>\$</b> 14	\$(352,833)	\$ 33,521

# Consolidated Statements of Cash Flows (In thousands)

	Years Ended December 31,					31,
		2007		2006		2005
Operating activities						
Net loss	\$	(53,076)	\$	(39,445)	\$	(27,363)
Adjustments to reconcile net loss to net cash used for operating activities:						
Depreciation and amortization		1,687		1,987		2,109
Loss on write-off/disposal of patents, property and equipment and						
licenses		934		420		405
Share-based compensation expense		4,821		5,051		20
Accretion of interest income, net		(227)		36		(125)
Changes in operating assets and liabilities:						
Prepaids and other current assets		(14)		(101)		(120)
Accounts payable		78		1,259		(589)
Accrued clinical/regulatory expenses		4,752		1,303		(420)
Accrued expenses		(473)		(147)		(777)
Accrued payroll and related expenses		(66)		`487		(432)
Net cash used for operating activities		(41,584)		(29,150)		(27,292)
1.44 4451 4544 154 Springs 444 414 5 1		(11,001)		(,)		(=:,=>=)
Investing activities						
Purchases of short-term investments		(51,415)		(16,700)		(82,350)
Sales of short-term investments.		55,750		44,050		36,236
Additions to property and equipment		(354)		(335)		(123)
Increase in patent costs and other assets		(628)		(536)		(361)
Net cash provided by (used for) investing activities	_	3,353		26,479		(46,598)
The oash provided by (asea for) investing activities in infiliation		3,333		20,112		(10,550)
Financing activities						
Net proceeds from issuance of common stock		38,673	,	353		78,449
Proceeds from issuance of notes payable		312		263		
Payments on obligations under notes payable		(209)		(527)		(995)
Payments on obligations under capital leases		(1)		(327)		(14)
Net cash provided by financing activities		38,775		89		77,440
Not easil provided by illiancing activities		56,775		0)		11,770
Increase (decrease) in cash and cash equivalents		544		(2,582)		3,550
Cash and cash equivalents at beginning of period		3,829		6,411		2,861
Cash and cash equivalents at end of period	\$	4,373	\$	3,829	\$	6,411
Cash and Cash equivalents at end of period	\$	4,373	Ф	3,029	Þ	0,411
Contribution and all discourses of a sub-flower to Comments of						
Supplemental disclosure of cash flow information:	•	02	æ	4.0	æ	116
Interest paid		82	\$	46_	<u> </u>	116
Supplemental schedule of noncash investing and financing activities:	•		•			
Capital lease obligations incurred for property and equipment	<u>\$</u>	55	\$		\$	

#### Notes to Consolidated Financial Statements

#### 1. Organization and Summary of Significant Accounting Policies

#### Organization and Business Activity

La Jolla Pharmaceutical Company (the "Company") is a biopharmaceutical company dedicated to improving and preserving human life by developing innovative pharmaceutical products.

#### **Basis of Presentation**

The Company has a history of recurring losses from operations and has an accumulated deficit of \$352,833,000 as of December 31, 2007. As of December 31, 2007, the Company had available cash and cash equivalents and short-term investments totaling \$39,359,000 and working capital of \$29,881,000. As of March 6, 2008, there was insufficient demand at auctions for three of the Company's AAA rated U.S. government-backed student loan auction rate securities, representing approximately \$6,000,000. As a result of insufficient demand, these three securities may not be liquid. The Company may experience a similar situation with its other remaining asset-backed student loan auction rate security of \$4,000,000, which comes up for auction on March 24, 2008. See Note 9 for details on recent events affecting the liquidity of certain securities. Additionally, the Company will require additional cash funding to execute against its strategic plan for 2008. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business and this does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company is actively seeking additional funding, including through collaborative arrangements and, through the public and/or private financings, to finance its continuing development efforts and to commercialize its technologies. The Company believes that additional funds can be obtained in the near future; however, there is no assurance such funds will be available to the Company when needed or that such funds would be available under favorable terms. In the event that the Company cannot obtain additional funds in the near future, the Company has the ability and intent to cut back on certain expenditures and/or reduce its operations including halting its ongoing Phase 3 clinical trial of Riquent and significantly reducing its workforce, which would have an adverse impact on completing its development efforts in a timely manner.

#### Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, La Jolla Limited, which was incorporated in England in October 2004. There have been no significant transactions related to La Jolla Limited since its inception.

#### Use of Estimates

The preparation of consolidated financial statements in conformity with United States generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and disclosures made in the accompanying notes to the consolidated financial statements. Actual results could differ materially from those estimates.

#### Cash, Cash Equivalents and Short-Term Investments

Cash and cash equivalents consist of cash and highly liquid investments which include money market funds and debt securities with maturities from purchase date of three months or less and are stated at market. Short-term investments mainly consist of debt securities with maturities from purchase date of greater than three months. In accordance with Statement of Financial Accounting Standard ("SFAS") No. 115, Accounting for Certain

#### Notes to Consolidated Financial Statements

#### 1. Organization and Summary of Significant Accounting Policies (continued)

Investments in Debt and Equity Securities, management has classified the Company's cash equivalents and short-term investments as available-for-sale securities in the accompanying consolidated financial statements. Available-for-sale securities are stated at fair market value, with unrealized gains and losses reported in other comprehensive income (loss). Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in interest income and have been immaterial for each of the years presented. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

#### Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, accounts payable and accrued expenses, are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments. Short-term investments are carried at fair value. None of the Company's debt or capital lease instruments that were outstanding at December 31, 2007 have readily ascertainable market values; however, the carrying values are considered to approximate their fair values.

#### Concentration of Risk

Cash, cash equivalents and short-term investments are financial instruments which potentially subject the Company to concentrations of credit risk. The Company deposits its cash in financial institutions. At times, such deposits may be in excess of insured limits. The Company invests its excess cash primarily in government-asset-backed securities, obligations of government agencies and money market funds. The Company has established guidelines relative to the diversification of its cash investments and their maturities in an effort to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

As of March 6, 2008, there was insufficient demand at auctions for three of the Company's AAA rated U.S. government-backed student loan auction rate securities, representing approximately \$6,000,000. As a result of insufficient demand, these three securities may not be liquid and the interest rates have been reset to the security's maximum rate. The Company may experience a similar situation with its other remaining asset-backed student loan auction rate security of \$4,000,000, which comes up for auction on March 24, 2008. To date, the Company has not recognized any realized losses on these securities. See Note 9 for details on recent events affecting the liquidity of certain securities.

#### Impairment of Long-Lived Assets and Assets to Be Disposed Of

In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through the undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and records the impairment as a reduction in the carrying value of the related asset and a charge to operating results. Estimating the undiscounted future cash flows associated with long-lived assets requires judgment and assumptions that could differ materially from the actual results. Although the Company believes its current and historical operating and cash flow losses are indicators of impairment, the Company believes the future cash flows to be received from the long-lived assets will exceed the assets' carrying value. The Company recognized approximately \$152,000 and \$104,000 in impairment losses for the years ended December 31, 2005 and December 31, 2006, respectively, and no impairment losses for the year ended December 31, 2007.

#### Notes to Consolidated Financial Statements

#### 1. Organization and Summary of Significant Accounting Policies (continued)

#### **Property and Equipment**

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets (primarily five years). Leasehold improvements and equipment under capital leases are stated at cost and depreciated on a straight-line basis over the shorter of the estimated useful life or the lease term.

Property and equipment is comprised of the following (in thousands):

		31,		
		2007		2006
Laboratory equipment	\$	6,498	\$	6,347
Computer equipment and software		4,727		4,682
Furniture and fixtures		491		488
Leasehold improvements		3,273		3,268
		14,989		14,785
Less: Accumulated depreciation		(13,718)		(12,452)
	\$	1,271	\$	2,333

Depreciation expense for the years ended December 31, 2007, 2006 and 2005 was \$1,471,000, \$1,840,000, and \$1,991,000, respectively.

#### **Patents**

The Company has filed numerous patent applications with the United States Patent and Trademark Office and in foreign countries. Legal costs and expenses incurred in connection with pending patent applications have been capitalized. Costs related to successful patent applications are amortized using the straight-line method over the lesser of the remaining useful life of the related technology or the remaining patent life, commencing on the date the patent is issued. Total successful patent application costs and accumulated amortization were \$2,492,000 and \$911,000 at December 31, 2007 and \$2,102,000 and \$734,000 at December 31, 2006, respectively. Total pending patent application costs were \$1,004,000 and \$1,761,000 at December 31, 2007 and 2006, respectively. Capitalized costs related to patent applications are charged to operations at the time a determination is made not to pursue such applications. Amortization expense for the years ended December 31, 2007, 2006 and 2005 was \$207,000, \$139,000, and \$107,000, respectively. The expected future annual amortization expense of successful patent applications for each of the succeeding five years is estimated to be approximately \$215,000.

# Accrued Clinical/Regulatory Expenses

The Company reviews and accrues clinical trial and regulatory-related expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. The Company follows this method since reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. Accrued clinical/regulatory costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development costs; however, a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to the Company's results of operations.

#### **Share-Based Compensation**

On January 1, 2006, the Company adopted SFAS No. 123R, Share-Based Payment ("SFAS 123R"), which is a revision of SFAS No. 123, Accounting and Disclosure of Stock-Based Compensation ("SFAS 123"). SFAS 123R requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including stock options, restricted stock and purchases under the La Jolla Pharmaceutical Company 1995 Employee Stock Purchase Plan (the "ESPP"), based on estimated fair values. SFAS 123R supersedes the Company's previous accounting under Accounting Principles Board Opinion ("APB") No. 25,

#### Notes to Consolidated Financial Statements

# 1. Organization and Summary of Significant Accounting Policies (continued)

Accounting for Stock Issued to Employees ("APB 25"), and SFAS 123, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin ("SAB") No. 107 ("SAB 107"), which discusses the interaction between SFAS 123R and certain SEC rules and regulations and provides the SEC's staff views regarding the valuation of share-based payment arrangements for public companies.

The Company has applied the provisions of SAB 107, related to the calculation of its expect term, in its adoption of SFAS 123R.

The Company adopted SFAS 123R using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's fiscal year 2006. The Company's Consolidated Statements of Operations as of and for the years ended December 31, 2006 and 2007 reflect the impact of SFAS 123R. In accordance with the modified prospective transition method, the Company's Consolidated Statements of Operations for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123R. Share-based compensation expense recognized under SFAS 123R for the years ended December 31, 2007 and 2006, respectively was approximately \$4,810,000 and \$5,048,000. As of December 31, 2007, there was approximately \$6,933,000 of total unrecognized compensation cost related to non-vested share-based payment awards granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. The Company expects to recognize that cost over a weighted-average period of 1.1 years.

Prior to January 1, 2006, the Company had adopted the disclosure-only provision of SFAS 123. Accordingly, the Company had not previously recognized compensation expense, except for compensation expense related to stock options granted to consultants and restricted stock granted to certain members of management.

Options or stock awards issued to non-employees, other than non-employee directors, have been determined in accordance with Emerging Issues Task Force 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Deferred charges for options granted to such non-employees are periodically remeasured as the options vest. In September and October 2007, the Company granted non-qualified stock options to purchase a total of 12;000 shares of common stock to consultants at an exercise price equal to the fair market value of the stock at the date of each grant. The Company recognized compensation expense for these stock option grants of approximately \$11,000 for the year ended December 31, 2007. In both January 2006 and January 2005, the Company granted a non-qualified stock option to purchase 1,000 shares of common stock to a consultant at an exercise price equal to the fair market value of the stock at the date of the grant. The Company recognized compensation expense for these stock option grants of approximately \$3,000 and \$8,000 for the year ended December 31, 2006 and 2005, respectively.

The table below reflects net loss (in thousands) and basic and diluted net loss per share for the year ended December 31, 2005 assuming the Company determined compensation expense in accordance with SFAS 123:

Veer Ended

	December 31, 2005
Net loss as reported	\$ (27,363)
Share-based compensation expense determined under fair value based method for all awards	(3,843)
Pro forma net loss	\$ (31,206)
Basic and diluted net loss per share—as reported	\$ (1.77)
Basic and diluted net loss per share—pro forma	<u>\$</u> (2.02)

The assumptions used to calculate share-based compensation expense for 2005 are discussed below.

SFAS 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods as share-based compensation expense in the Company's Consolidated Statements of Operations. For the years ended December 31, 2007 and 2006, the Company's Consolidated Statement of Operations included compensation expense for share-based payment awards granted prior to, but not

#### Notes to Consolidated Financial Statements

#### 1. Organization and Summary of Significant Accounting Policies (continued)

yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. Compensation expense for all share-based payment awards granted prior to the adoption of SFAS 123R will continue to be recognized using the straight-line single-option method of attributing the value of share-based compensation to expense. Compensation expense for all share-based payment awards granted after December 31, 2005 is recognized using the straight-line single-option method. As share-based compensation expense recognized in the Consolidated Statement of Operations for the fiscal years 2007 and 2006 is based on awards ultimately expected to vest, share-based compensation expense has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In the Company's pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

As permitted by SFAS 123R, the Company utilizes the Black-Scholes option-pricing model as its method of valuation for stock options and purchases under the ESPP. The Black-Scholes model was previously utilized for the Company's pro forma information required under SFAS 123. The Company's determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the Company's stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company's expected stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors.

#### Valuation and Expense Information Under SFAS 123R and APB 25

The following table summarizes share-based compensation expense (in thousands) related to employee and director stock options, restricted stock and ESPP purchases under SFAS 123R for the years ended December 31, 2007 and 2006:

	December 51	
· · · · · · · · · · · · · · · · · · ·	2007	2006
Research and development	\$ 1,907	\$ 1,833
General and administrative	2,903	3,215
Share-based compensation expense included in operating expenses	<u>\$ 4,810</u>	<u>\$_5,048</u>

December 31

For the years ended December 31, 2007, 2006, and 2005 the Company estimated the fair value of each option grant and ESPP purchase right on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

#### Options:

• •	December 31,			
	2007	2006	2005	
Risk-free interest rate	4.7%	4.8%	4.1%	
Dividend yield	0.0%	0.0%	0.0%	
Volatility	118.0%	113.7%	119.0%	
Expected life (years)	6.0	5.9	5.9	

#### Notes to Consolidated Financial Statements

#### 1. Organization and Summary of Significant Accounting Policies (continued)

ESPP.

	December 31,			
	2007	2006	2005	
Risk-free interest rate	4.5%	4.8%	4.1%	
Dividend yield	0.0%	0.0%	0.0%	
Volatility	67.8%	46.4%	125.4%	
Expected life (years)	3 months	3 months	5.9	

The weighted-average fair values of options granted were \$3.71, \$3.92, and \$2.81 for the years ended December 31, 2007, 2006 and 2005, respectively. The weighted-average purchase prices of shares purchased through the ESPP were \$2.69, \$2.98, and \$3.04 for the years ended December 31, 2007, 2006 and 2005, respectively.

The risk-free interest rate assumption is based on observed interest rates appropriate for the term of the Company's employee and director stock options and ESPP purchases. The dividend yield assumption is based on the Company's history and expectation of dividend payouts. The Company has never paid dividends on its common stock and the Company does not anticipate paying dividends in the foreseeable future.

The Company used historical stock price volatility as the expected volatility assumption required in the Black-Scholes option-pricing model consistent with SFAS 123R. Prior to fiscal 2006, the Company used its historical stock price volatility in accordance with SFAS 123 for purposes of its pro forma information. The selection of the historical volatility approach was based on the availability of historical stock prices for the duration of the awards' expected term and the Company's assessment that historical volatility is more representative of future stock price trends than other available methods.

The expected life of employee and director stock options represents the weighted-average period the stock options are expected to remain outstanding. Under the SAB 107 simplified method, the expected life calculated by the Company for option grants made during the year ended December 31, 2007 was 6.0 — 6.1 years for the new and existing employee grants and 5.5 years for the director grants. The expected life calculated by the Company for option grants made during the year ended December 31, 2006 was 5.8 years for the new and existing employee grants, 6.1 years for the new officer grants, and 5.3 — 6.0 years for the director grants. The expected life for ESPP purchase rights represents the length of each purchase period. Because employees purchase stock quarterly, the expected term for ESPP purchase rights is three months for shares purchased during the years ended December 31, 2007 and 2006. Prior to the adoption of SFAS 123R on January 1, 2006, the Company utilized an estimate of expected life for ESPP that was consistent with its estimate for options.

Because share-based compensation expense recognized in the Consolidated Statement of Operations for fiscal years 2007 and 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. In the Company's pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

#### Notes to Consolidated Financial Statements

#### 1. Organization and Summary of Significant Accounting Policies (continued)

#### Restricted Stock

On December 14, 2005, the Company issued 83,518 shares of restricted stock to certain members of management in exchange for services provided over the vesting period, pursuant to certain retention agreements dated October 6, 2005. The shares of restricted stock fully vested (i.e., the restrictions lapsed) one year from the date of grant and were subject to repurchase by the Company until the one-year anniversary of the date of issuance. Pursuant to a separation agreement dated March 17, 2006, the Company's repurchase right with respect to 29,120 shares of restricted stock granted to the former Chairman and Chief Executive Officer immediately lapsed upon his resignation on March 14, 2006. As such and in accordance with his retention agreement, the Company accelerated the vesting of these shares of restricted stock. In addition, the remaining 54,398 shares of restricted stock fully vested on December 14, 2006, the one-year anniversary of the date of issuance, and therefore the Company's repurchase right with respect to these shares of restricted stock has lapsed.

On March 15, 2006, the Company issued 20,000 shares of restricted stock to the new Chairman of the Board in exchange for services provided over the vesting period. The shares of restricted stock vested with respect to 10,000 shares six months after the issuance date and will vest with respect to the remaining 10,000 shares upon the first anniversary of the issuance date. On September 15, 2006 and March 15, 2007, the vesting provisions with respect to the 20,000 shares of restricted stock were met and therefore the Company's repurchase rights lapsed.

In both December 2006 and March 2007, the Company issued an additional 3,600 shares of restricted stock to the Chairman of the Board in accordance with the Chairman Compensation Policy approved by the Board of Directors on March 14, 2006 regarding the tax liability associated with the restricted stock issued on March 15, 2006 and vested on September 15, 2006 and March 15, 2007. All of these additional shares of restricted stock immediately vested on the date of issuance.

In accordance with SFAS 123R, the Company recognized approximately \$36,000, \$381,000, and \$12,000, respectively, in compensation expense for the restricted stock grants noted above for the years ended December 31, 2007, 2006, and 2005 which includes compensation expense for the acceleration of vesting.

#### **Reverse Stock Split**

On December 12, 2005, the Company's stockholders approved a one-for-five reverse stock split of the Company's common stock, effective as of the close of business on December 21, 2005. All share and per share figures presented herein have been adjusted to reflect the reverse stock split, except for shares of authorized common stock.

#### Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted-average number of common shares outstanding during the periods in accordance with SFAS No. 128, *Earnings per Share* and SAB No. 98. Basic earnings per share ("EPS") is calculated by dividing the net income or loss by the weighted-average number of common shares outstanding for the period, without consideration for common share equivalents. Diluted EPS is computed by dividing the net income or loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options, common stock subject to repurchase by the Company, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

#### Notes to Consolidated Financial Statements

#### 1. Organization and Summary of Significant Accounting Policies (continued)

Because the Company has incurred a net loss for all three years presented in the Consolidated Statements of Operations, stock options, common stock subject to repurchase and warrants are not included in the computation of net loss per share because their effect is anti-dilutive. The shares used to compute basic and diluted net loss per share represent the weighted-average common shares outstanding, reduced by the weighted-average unvested common shares subject to repurchase. There were no unvested common shares subject to repurchase for the year ended December 31, 2007. The number of weighted-average unvested common shares subject to repurchase for the years ended December 31, 2006 and December 31, 2005 were 8,000 and 4,119, respectively.

#### Comprehensive Loss

In accordance with SFAS No. 130, Reporting Comprehensive Income (Loss), unrealized gains and losses on available-for-sale securities are included in other comprehensive income.

#### **Recently Issued Accounting Standards**

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, Fair Value Measurements ("SFAS 157"). SFAS 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice resulting from the application of SFAS 157 relate to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company is currently assessing the impact of SFAS 157 on its consolidated results of operations and financial condition.

In February 2007, FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115 ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the impact of SFAS 159 on its consolidated results of operations and financial condition.

In June 2007, FASB ratified the consensus reached by the Emerging Issues Task Force ("EITF") on EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities ("ETF 07-3"). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal year beginning after December 15, 2007. The adoption of EITF 07-3 is not expected to have a material effect on the Company's consolidated financial statements.

#### Notes to Consolidated Financial Statements

#### 2. Cash Equivalents and Short-term Investments

The following is a summary of the Company's available-for-sale securities (in thousands):

	Amortized				nortized Unrealized Unrealized		nortized Unrealized Unrealized		Amortized Unrealized Unrealized		Amortized Unrealized Unrea		Esti	mated Fair Value
December 31, 2007  Money market accounts  Obligations of United States government agencies	\$	2,051 6,916	\$	<u></u>	\$		\$	2,051 6,930						
Asset-backed auction rate securities	<u> </u>	28,056 37,023			<u> </u>		\$	28,056 37,037						
	Ψ	31,023		ross		iross	Ψ.	31,031						
	_A	mortized Cost	Unr	ealized ains	Uni	ealized osses	Esti	mated Fair Value						
Money market accounts	\$	2,189 12,024	\$	_	\$	_	\$	2,189 12.024						
Asset-backed auction rate securities	<u> </u>	27,056 41,269	•		•			27,056 41,269						

The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Included in cash and cash equivalents at December 31, 2007 and 2006 were \$2,051,000 and \$2,189,000, respectively, of securities classified as available-for-sale as the Company expects to sell them in order to support its current operations regardless of their maturity date. As of December 31, 2007, available-for-sale securities and cash equivalents of \$8,981,000 mature in one year or less and \$28,056,000 are due after one year. Securities that have a maturity date greater than one year have their interest rate reset periodically within time periods not exceeding 92 days. See Note 9 to the consolidated financial statements for subsequent events related to the Company's asset-backed auction rate securities.

#### 3. Commitments

#### Leases

In July 1992, the Company entered into a non-cancelable operating lease for the rental of its research and development laboratories and clinical manufacturing facilities. In October 1996, the Company entered into an additional non-cancelable operating lease for additional office space. In 2004, the Company exercised its options to extend these leases until July 2009.

In September 2002, the Company entered into an additional non-cancelable operating lease for additional research space. In July 2006, the Company extended the term of this lease until December 2006. This lease expired on December 31, 2006.

In July 2003, the Company entered into a capital lease agreement for \$111,000 to finance the purchase of certain equipment. The agreement was secured by the equipment, bore interest at 7.00% per annum, and was payable in quarterly installments of principal and interest of approximately \$15,000 for eight quarters. The final quarterly installment was made in March 2005.

In October 2007, the Company entered into a capital lease agreement for \$55,000 to finance the purchase of certain equipment. The agreement is secured by the equipment, bears interest at 10.00% per annum, and is payable in monthly installments of principal and interest of approximately \$1,000 for 60 months.

#### Notes to Consolidated Financial Statements

#### 3. Commitments (continued)

Annual future minimum lease payments as of December 31, 2007 are as follows (in thousands):

	Operating Ca		pital	
Years ended December 31,	Leases		Leases	
2008	\$	830	\$	15
2009		543		14
2010		34		14
2011		17		14
2012 and there-after	_			12
Total	<u>\$</u>	1,424	\$	69
Less amount representing interest				<u>(15</u> )
Present value of net minimum lease payments				54
Less current portion			_	10
Noncurrent portion of capital lease obligations			<u>\$</u>	<u>44</u>

Rent expense under all operating leases totaled \$869,000, \$1,065,000 and \$1,046,000 for the years ended December 31, 2007, 2006 and 2005, respectively. Equipment acquired under capital leases included in property and equipment totaled \$54,000 (net of accumulated amortization of \$1,000) at December 31, 2007. Amortization expense associated with this equipment is included in depreciation and amortization expense for the period ended December 31, 2007. There was no equipment under capital leases included in property and equipment as of December 31, 2006.

#### **Purchase Obligations**

As of December 31, 2007, the Company had total purchase obligations of approximately \$1,412,000, which consisted of non-cancelable purchase commitments with third-party manufacturers of materials to be used in the production of Riquent. For the year ended December 31, 2007, approximately \$763,000 of the total purchase obligations were not included in the Company's consolidated financial statements. The Company intends to use its current financial resources to fund its obligations under these purchase commitments.

#### 4. Long-Term Debt

The following is a summary of the notes payable obligations that are secured by the financed equipment of approximately \$833,000 as of December 31, 2007:

			Original Note
Data of Nata	Interest Rate (%)	Monthly Payments	Amount (in thousands)
Date of Note			
September 28, 2004	8.44	First 36 months at \$5,000; last six months at \$1,000	157
December 28, 2006	10.56	First 36 months at \$8,000; last 12 months at \$3,000	263
June 28, 2007		First 36 months at \$2,000; last 12 months at \$500	75
December 31, 2007	10.55	\$6,000 for 48 months	<u>236</u>
,		,	\$ 731

#### Notes to Consolidated Financial Statements

#### 4. Long-Term Debt (continued)

Annual future minimum notes payable payments as of December 31, 2007 are as follows (in thousands):

Years ended December 31,		łotes yable
2008	\$	179
2009		193
2010		127
2011		69
Total		568
Less amount representing interest	_	<u>(86</u> )
Present value of net minimum notes payable payments		482
Less current portion		<b>(138)</b>
Noncurrent portion of notes payable	<u>\$</u>	344

#### 5. Restructuring Charges

In March 2005, the Company restructured its operations in order to reduce costs. In accordance with SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities, the Company recorded total restructuring charges of approximately \$1,488,000 in connection with the termination of 60 employees (approximately \$1,174,000), the impairment of certain long-term assets (approximately \$152,000), and retention payments for key executives (approximately \$162,000). This action followed an announcement by the Company in March 2005 that, based on the outcome of a meeting with the FDA, the Company's lead drug candidate, Riquent, was unlikely to receive accelerated approval under the FDA's Subpart H regulation.

In fiscal 2005, approximately \$991,000 of the total restructuring charges was included in research and development expense and approximately \$497,000 was included in general and administrative expense. The restructuring plan was completed in September 2005 and actual total charges paid were approximately \$1,336,000. The non-cash charge of \$152,000 for write-downs of impaired assets as a result of the restructuring was included in research and development expense in the first quarter of 2005.

#### 6. Stockholders' Equity

#### **Preferred Stock**

As of December 31, 2007, the Company's Board of Directors is authorized to issue 8,000,000 shares of preferred stock with a par value of \$0.01 per share, in one or more series.

The Company's Certificate of Designation filed with the Secretary of State of the State of Delaware designates 100,000 shares of preferred stock as nonredeemable Series A Junior Participating Preferred Stock ("Series A Preferred Stock"). Pursuant to the terms of the Company's Stockholder Rights Plan, in the event of liquidation, each share of Series A Preferred Stock is entitled to receive, subject to certain restrictions, a preferential liquidation payment of \$1,000 per share plus the amount of accrued unpaid dividends. The Series A Preferred Stock is subject to certain anti-dilution adjustments, and the holder of each share is entitled to 1,000 votes, subject to adjustments. Cumulative quarterly dividends of the greater of \$0.25 or, subject to certain adjustments, 1,000 times any dividend declared on shares of common stock, are payable when, as and if declared by the Board of Directors, from funds legally available for this purpose.

#### Notes to Consolidated Financial Statements

#### 6. Stockholders' Equity (continued)

#### Warrants

In connection with the December 2005 private placement, the Company issued warrants to purchase 4,399,992 shares of the Company's common stock. The warrants were immediately exercisable upon grant, have an exercise price of \$5.00 per share and remain exercisable for five years. As of December 31, 2007, all of the warrants were outstanding and 4,399,992 shares of common stock are reserved for issuance upon exercise of the warrants.

#### Restricted Stock

On December 14, 2005, the Company issued 83,518 shares of restricted stock to certain members of management in exchange for services provided over the vesting period, pursuant to certain retention agreements dated October 6, 2005. The shares of restricted stock fully vested (i.e., the restrictions lapsed) one year from the date of grant and were subject to repurchase by the Company until the one-year anniversary of the date of issuance. Pursuant to a separation agreement dated March 17, 2006, the Company's repurchase right with respect to 29,120 shares of restricted stock granted to the former Chairman and Chief Executive Officer immediately lapsed upon his resignation on March 14, 2006. As such and in accordance with his retention agreement, the Company accelerated the vesting of these shares of restricted stock. In addition, the remaining 54,398 shares of restricted stock fully vested on December 14, 2006, the one-year anniversary of the date of issuance, and therefore the Company's repurchase right with respect to these shares of restricted stock has lapsed.

On March 15, 2006, the Company issued 20,000 shares of restricted stock to the new Chairman of the Board in exchange for services provided over the vesting period. The shares of restricted stock vested with respect to 10,000 shares six months after the issuance date and will vest with respect to the remaining 10,000 shares upon the first anniversary of the issuance date. On September 15, 2006 and March 15, 2007, the vesting provisions with respect to the 20,000 shares of restricted stock were met and therefore the Company's repurchase rights lapsed.

In both December 2006 and March 2007, the Company issued an additional 3,600 shares of restricted stock to the Chairman of the Board in accordance with the Chairman Compensation Policy approved by the Board of Directors on March 14, 2006 regarding tax liability associated with the restricted stock issued on March 15, 2006 and vested on September 15, 2006 and March 15, 2007. All of these additional shares of restricted stock immediately vested on the date of issuance.

In accordance with SFAS 123R, the Company recognized approximately \$36,000, \$381,000, and \$12,000, respectively, in compensation expense for the restricted stock grants noted above for the years ended December 31, 2007, 2006, and 2005, which includes compensation expense for the acceleration of vesting. The total fair value of the restricted stock grants vested in 2007 was approximately \$77,000 of which approximately \$41,000 was recognized in 2006 and approximately \$36,000 was recognized in 2007. The total fair value of the restricted stock grants vested in 2006 was approximately \$352,000 of which approximately \$12,000 was recognized in 2005 and approximately \$340,000 was recognized in 2006.

#### **Stock Option Plans**

In June 1994, the Company adopted the La Jolla Pharmaceutical Company 1994 Stock Incentive Plan (the "1994 Plan") under which, as amended, 1,640,000 shares of common stock (post-reverse stock split) were authorized for issuance. The 1994 Plan expired in June 2004 and there were 952,500 options outstanding under the 1994 Plan as of December 31, 2007.

#### Notes to Consolidated Financial Statements

# 6. Stockholders' Equity (continued)

In May 2004, the Company adopted the La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (the "2004 Plan") under which, as amended, 5,000,000 shares of common stock (post-reverse stock split) have been authorized for issuance. The 2004 Plan provides for the grant of incentive and non-qualified stock options, as well as other share-based payment awards, to employees, directors, consultants and advisors of the Company with up to a 10 year contractual life and various vesting periods as determined by the Company's compensation committee or the board of directors, as well as automatic fixed grants to non-employee directors of the Company. As of December 31, 2007, there were a total of 3,857,076 options outstanding and no unvested shares of restricted stock granted under the 2004 Plan and 864,400 shares remained available for future grant.

A summary of the Company's stock option activity (including shares of restricted stock) and related data follows:

		Outstanding Options			
	Options Available	Number of	Weighted- Average		
	For Grant	Shares	Exercise Price		
Balance at December 31, 2004	131,125	1,795,502	\$ 22.22		
Additional shares authorized	3,760,000	· · · · —	_		
Granted	(743,981)	743,981	\$ 3.35		
Restricted stock granted	(83,518)		_		
Exercised		(3,106)	\$ 2.37		
Cancelled	388,349	(388,349)	\$ 20.15		
Expired	(261,744)		_		
Balance at December 31, 2005	3,190,231	2,148,028	\$ 16.09		
Granted	(2,450,745)	2,450,745	\$ 4.58		
Restricted stock granted	(23,600)	_	_		
Exercised	<del></del>	(56,012)	\$ 2.25		
Cancelled	240,382	(240,382)	\$ 14.04		
Expired	(100,983)				
Balance at December 31, 2006	855,285	4,302,379	\$ 9.83		
Additional shares authorized	840,000	_	_		
Granted	(1,027,973)	1,027,973	\$ 4.30		
Restricted stock granted	(3,600)	_	_ '		
Exercised		(166,280)	\$ 3.01		
Cancelled	354,496	(354,496)	\$ 14.20		
Expired	(153,808)		_		
Balance at December 31, 2007	864,400	4,809,576	\$ 8.56		

For the year ended December 31, 2007, options cancelled (included in the above table) consisted of approximately 200,688 options forfeited with a weighted-average exercise price of \$5.32 and approximately 153,808 options expired with a weighted-average exercise price of \$25.80.

As of December 31, 2007, options exercisable have a weighted-average remaining contractual term of 6.1 years. The total intrinsic value of stock option exercises, which is the différence between the exercise price and closing price of the Company's common stock on the date of exercise, during the years ended December 31, 2007, 2006, and 2005 was \$500,000, \$74,000 and \$5,000, respectively. As of December 31, 2007 the total intrinsic value, which is the difference between the exercise price and closing price of the Company's common stock of options outstanding and exercisable was \$844,000 and \$469,000, respectively.

# Notes to Consolidated Financial Statements

# 6. Stockholders' Equity (continued)

	2007		Y	Years Ended December 31, 2006				200:	<u>;                                    </u>	
		Weighted- Average Exercise		Weighted- Average Exercise				A	eighted- verage xercise	
	Options	Price	_	Options		Price	_	Options	_	<u>Price</u>
Exercisable at end of year  Weighted-average fair value of	 2,808,588	\$ 11.44		1,859,139	\$	16.27		1,276,090	\$	22.24
options granted during the year	\$ 3.71		\$	3.92			\$	2.81		

Exercise prices and weighted-average remaining contractual lives for the options outstanding (excluding shares of restricted stock) as of December 31, 2007 were:

Options Outstanding	Range of Exercise Prices	Weighted- Average Remaining Contractual Life (in years)	Weighted- Average Exercise Price	Options Exercisable	Weighted- Average Exercise Price of Options Exercisable
645,050	\$ 1.72 — \$ 3.08	7.82	\$ 2.80	295,965	\$ 2.53
512,078	\$ 3.23 — \$ 4.01	8.63	\$ 3.70	225,189	\$ 3.69
339,787	\$ 4.03 — \$ 4.44	7.65	\$ 4.21	243,939	\$ 4.20
1,025,089	\$ 4.46	7.35	\$ 4.46	624,297	\$ 4.46
855,500	\$ 4.60 \$ 5.26	8.27	\$ 5.23	378,834	\$ 5.26
460,199	\$ 5.28 — \$ 14.00	8.44	\$ 6.58	68,491	\$ 11.58
449,566	\$ 14.50 — \$ 23.13	4.38	\$ 17.08	449,566	\$ 17.08
522,307	\$ 23.55 — \$ 60.31	4.15	\$ 31.16	522,307	\$ 31.16
4,809,576	\$ 1.72 — \$ 60.31	7.21	\$ 8.56	2,808,588	<u>\$ 11.44</u>

At December 31, 2007, the Company has reserved 5,673,976 shares of common stock for future issuance upon exercise of options granted or to be granted under the 1994 and 2004 Plans.

# **Employee Stock Purchase Plan**

Effective August 1, 1995, the Company adopted the ESPP under which, as amended, 700,000 shares of common stock are reserved for sale to eligible employees, as defined in the ESPP. Employees may purchase common stock under the ESPP every three months (up to but not exceeding 10% of each employee's base salary, or hourly compensation, and any cash bonus paid, subject to certain limitations) over the offering period at 85% of the fair market value of the common stock at specified dates. The offering period may not exceed 24 months. During the years ended December 31, 2007 and 2006, 97,104 and 80,017 shares of common stock were issued under the ESPP, respectively. As of December 31, 2007, 529,086 shares of common stock have been issued under the ESPP and 170,914 shares of common stock are available for future issuance.

	Years Ended December 31.		
	2007	2006	2005
Weighted-average fair value of Employee Stock Purchase Plan purchases	\$ 1.47	\$ 1.48	\$ 0.59

#### Notes to Consolidated Financial Statements

# 6. Stockholders' Equity (continued)

## Stockholder Rights Plan

The Company has adopted a Stockholder Rights Plan (the "Rights Plan"), which was amended in July 2000, December 2005 and March 2006. The Rights Plan provides for a dividend of one right (a "Right") to purchase fractions of shares of the Company's Series A Preferred Stock for each share of the Company's common stock. Under certain conditions involving an acquisition by any person or group of 15% or more of the common stock (or in the case of State of Wisconsin Investment Board, 20% or more, Essex Woodland Health Ventures Fund V, L.P., 29% or more, Frazier Healthcare V, L.P., 19% or more, or Alejandro Gonzalez, 19% or more), the Rights permit the holders (other than the 15% holder, or, in the case of State of Wisconsin Investment Board, 20% holder, Essex Woodland Health Ventures Fund V, L.P., 29% holder, Frazier Healthcare V, L.P., 19% holder, or Alejandro Gonzalez, 19% holder) to purchase the Company's common stock at a 50% discount upon payment of an exercise price of \$30 per Right. In addition, in the event of certain business combinations, the Rights permit the purchase of the common stock of an acquirer at a 50% discount. Under certain conditions, the Rights may be redeemed by the Board of Directors in whole, but not in part, at a price of \$0.001 per Right. The Rights have no voting privileges and are attached to and automatically trade with the Company's common stock. The Rights expire on December 2, 2008.

# 7. 401(k) Plan

The Company has established a 401(k) defined contribution retirement plan (the "401(k) Plan"), which was amended in May 1999 to cover all employees. The 401(k) Plan was also amended in December 2003 to increase the voluntary employee contributions from a maximum of 20% to 50% of annual compensation (as defined). This increase was effective beginning January 1, 2004. The Company does not match employee contributions or otherwise contribute to the 401(k) Plan.

#### 8. Income Taxes

On July 13, 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes ("FIN 48"), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. FIN 48 prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken in a tax return. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted the provisions of FIN 48 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption and there are no unrecognized tax benefits included in the balance sheet at December 31, 2007, that would, if recognized, affect the effective tax rate.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's consolidated balance sheets at December 31, 2006 and at December 31, 2007, and has not recognized interest and/or penalties in the consolidated statement of operations for each of the three years in the period ended December 31, 2007.

The Company is subject to taxation in the United States and various state jurisdictions. The Company's tax years for 1993 and forward are subject to examination by the United States and California tax authorities due to the carry forward of unutilized net operating losses and research and development credits.

# Notes to Consolidated Financial Statements

# 8. Income Taxes (continued)

The Company is currently undergoing a Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Until this analysis has been completed the Company has removed the deferred tax assets for net operating losses of \$120,445,000 and research and development credits of \$21,112,000 generated through 2007 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits under FIN No. 48. The Company expects the Section 382 analysis to be completed within the next twelve months. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

At December 31, 2007, the Company had federal and California income tax net operating loss carryforwards of approximately \$316,089,000 and \$169,422,000, respectively. The difference between the federal and California tax loss carryforwards is primarily attributable to the capitalization of research and development expenses for California income tax purposes. In addition, the Company has federal and California research and development tax credit carryforwards of \$15,344,000 and \$8,874,000, respectively. The federal net operating loss and research tax credit carryforwards will begin to expire in 2008 unless previously utilized. The California net operating loss carryforwards will begin to expire in 2009 unless previously utilized. The California research and development credit carryforwards will carry forward indefinitely until utilized.

Significant components of the Company's deferred tax assets as of December 31, 2007 and 2006 are listed below. A valuation allowance of \$10,923,000 and \$131,496,000 at December 31, 2007 and 2006, respectively, has been recognized to offset the net deferred tax assets as realization of such assets is uncertain. Amounts are shown in thousands as of December 31 of the respective years:

	December 31,		· 31,	
	2	2007		2006
Deferred tax assets:				
Net operating loss carryforwards	\$		\$	104,705
Research and development credits				19,100
Capitalized research and development and other	1	10,923		7,691
Total deferred tax assets		0,923		131,496
Net deferred tax assets	1	0,923		131,496
Valuation allowance for deferred tax assets	(1	0,923)		(131,496)
Net deferred taxes	\$		\$	

# 9. Subsequent Events

The recent conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to the security's maximum rate. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature.

The Company reduced the amount of investments held in auction rate securities from \$28,056,000 to \$10,000,000 subsequent to year-end through the successful sale of \$18,056,000 of investments in auction rate securities at par value. As of March 6, 2008, there was insufficient demand at auctions for three of the Company's AAA rated U.S. government-backed student loan auction rate securities, representing approximately \$6,000,000 of the \$10,000,000 auction rate securities then outstanding. As a result of insufficient demand, these three securities may not be liquid and the interest rates have been reset to the security's maximum rate. The Company may experience a similar situation with its other remaining asset-backed student loan auction rate security of \$4,000,000, which comes up for auction on March 24, 2008. If the credit ratings of the security issuers deteriorate and any decline in market value is determined to be other-than-temporary, the Company would be required to adjust the carrying value of the investment through an impairment charge. To date, the Company has not recognized any realized losses on these securities.

# Notes to Consolidated Financial Statements

# 10. Selected Quarterly Financial Data (unaudited)

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2007 and 2006 (in thousands except per share amounts):

	Quarters Ended							
		Mar. 31, Jun. 30, Sept. 30,			Dec. 31,			
2007								
Expenses: Research and development	\$	1,980		2,112		2,585	\$	12,626 2,381
Loss from operations		(12,355)		(14,298)		(14,033)		(15,007)
Interest income, net		485		781		744		607
Net loss	\$	(11,870)	\$	(13,517)	\$	(13,289)	\$	(14,400)
Basic and diluted net loss per share								(0.36)
Shares used in computing basic and diluted net loss per share		32,737		39,256	_	39,577		39,607
2006								
Expenses: Research and development		3,725				7,687 1,546 (9,233)		9,174 2,116 (11,290)
Interest income, net	_	747		742		695		596
Net loss	<u>\$</u>	(10,868)	\$	(9,345)	\$	(8,538)	\$	(10,694)
Basic and diluted net loss per share	<u>\$</u>	(0.33)	\$	(0.29)	\$	(0.26)	\$	(0.33)
Shares used in computing basic and diluted net loss per share		32,480		32,503		32,534		32,660

# EXHIBIT INDEX

Exhibit Number 3.1	Description Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (2)
3.3	Form of Common Stock Certificate (3)
4.1	Rights Agreement, dated as of December 3, 1998, between the Company and American Stock Transfer & Trust Company (4)
4.2	Amendment No. 1 to the Rights Agreement, dated as of July 21, 2000, between the Company and American Stock Transfer & Trust Company (5)
4.3	Amendment No. 2 to the Rights Agreement, dated as of December 14, 2005, between the Company and American Stock Transfer & Trust Company (6)
4.4	Amendment No. 3 to the Rights Agreement, dated as of March 1, 2006, between the Company and American Stock Transfer & Trust Company (1)
10.1	Form of Indemnification Agreement (7)*
10.2	Industrial Real Estate Lease, effective July 27, 1992, by and between the Company and BRE Properties, Inc. (8)
10.3	First Amendment to Lease, dated March 15, 1993, by and between the Company and BRE Properties, Inc. (8)
10.4	Second Amendment to Lease, dated July 18, 1994, by and between the Company and BRE Properties, Inc. (9)
10.5	Third Amendment to Lease, dated January 26, 1995, by and between the Company and BRE Properties, Inc. (10)
10.6	Fourth Amendment to Lease, dated July 8, 2004, by and between the Company and EOP-Industrial Portfolio, LLC (11)
10.7	Building Lease Agreement, effective November 1, 1996, by and between the Company and WCB II-S BRD Limited Partnership (12)
10.8	First Amendment to Lease, dated May 4, 2001, by and between the Company and Spieker Properties, L.P. (11)
10.9	Second Amendment to Lease, dated July 8, 2004, by and between the Company and EOP-Industrial Portfolio, LLC (11)
10.10	La Jolla Pharmaceutical Company 1994 Stock Incentive Plan (Amended and Restated as of May 16, 2003) (13)*
10.11	La Jolla Pharmaceutical Company 1995 Employee Stock Purchase Plan (Amended and Restated as of May 24, 2007) (33)*
10.12	La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (Amended and Restated as of May 24, 2007 (33)*
10.13	Form of Option Grant under the La Jolla Pharmaceutical Company 2004 Equity Incentive Plan (15)*
10.14	Reserved.

Exhibit Number 10.15	Description Reserved.
10.16	Steven B. Engle Employment Agreement (8)*
10.17	Amendment No. 1 to Steven B. Engle Employment Agreement (16)*
10.18	Amendment No. 2 to Steven B. Engle Employment Agreement (17)*
10.19	Amendment No. 3 to Steven B. Engle Employment Agreement (13)*
10.20	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Matthew Linnik, Ph.D. (1)*
10.21	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Bruce Bennett, Jr. (1)*
10.22	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Josefina Elchico (1)*
10.23	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Paul Jenn, Ph.D. (1)*
10.24	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Theodora Reilly (1)*
10.25	Amended and Restated Employment Agreement, dated February 23, 2006, by and between the Company and Gail Sloan (1)*
10.26	Supplement to employment offer letter for Kenneth R. Heilbrunn (18)*
10.27	Retention Agreement, dated October 6, 2005, by and between the Company and Steven B. Engle (19)*
10.28	Retention Agreement, dated October 6, 2005, by and between the Company and Matthew Linnik, Ph.D. (19)*
10.29	Retention Agreement, dated October 6, 2005, by and between the Company and Bruce Bennett (19)*
10.30	Retention Agreement, dated October 6, 2005, by and between the Company and Josefina T. Elchico (19)*
10.31	Retention Agreement, dated October 6, 2005, by and between the Company and Paul Jenn, Ph.D. (19)*
10.32	Retention Agreement, dated October 6, 2005, by and between the Company and Theodora Reilly (19)*
10.33	Retention Agreement, dated October 6, 2005, by and between the Company and Gail Sloan (19)*
10.34	Retention Agreement, dated October 6, 2005, by and between the Company and Andrew Wiseman, Ph.D. (19)*
10.35	Retention Agreement, dated October 6, 2005, by and between the Company and Lisa Koch (32)*
10.36	Underwriting Agreement, dated January 28, 2005, by and between the Company and Pacific Growth Equities, LLC (20)

Exhibit Number	Description
10.37	Underwriting Agreement, dated as of February 19, 2004, between the Company and Pacific Growth Equities, LLC (21)
10.38	Underwriting Agreement, dated as of August 7, 2003, between the Company and Pacific Growth Equities, LLC (22)
10.39	Registration Rights Agreement, dated October 6, 2005, between the Company and the initial purchasers (19)
10.40	Form of Registration Rights Agreement, dated January 2002, between the Company and the initial purchasers (23)
10.41	Form of Registration Rights Agreement, dated February 5, 2001, between the Company and the initial purchasers (24)
10.42	Form of Registration Rights Agreement, dated July 19, 2000, between the Company and the initial purchasers (24)
10.43	Form of Registration Rights Agreement, dated February 10, 2000, between the Company and the initial purchasers (24)
10.44	Securities Purchase Agreement, dated as of October 6, 2005, between the Company and the initial purchasers (19)
10.45	Form of Stock Purchase Agreement, dated January 2002, between the Company and the initial purchasers (23)
10.46	Form of Stock Purchase Agreement, dated February 5, 2001, between the Company and the initial purchasers (24)
10.47	Form of Stock Purchase Agreement, dated July 19, 2000, between the Company and the initial purchasers (24)
10.48	Form of Stock Purchase Agreement, dated February 10, 2000, between the Company and the initial purchasers (24)
10.51	Master Security Agreement, effective as of September 6, 2002, by and between the Company and General Electric Capital Corporation (25)
10.52	Promissory Note, dated as of December 28, 2006, by and between the Company and General Electric Capital Corporation (31)
10.53	Promissory Note, dated as of September 28, 2004, by and between the Company and General Electric Capital Corporation (26)
10.54	Promissory Note, dated as June 25, 2004, between the Company and General Electric Capital Corporation (11)
10.55	Promissory Note, dated as March 31, 2004, between the Company and General Electric Capital Corporation (27)
10.56	Promissory Note, dated as of December 18, 2003, between the Company and General Electric Capital Corporation (28)
10.57	Promissory Note, dated as of September 26, 2003, between the Company and General Electric Capital Corporation (24)
10.58	Promissory Note, dated as of June 27, 2003, between the Company and General Electric Capital Corporation (13)

Exhibit Number 10.59	Description Promissory Note, dated as of April 23, 2003, between the Company and General Electric Capital Corporation (29)
10.60	Promissory Note, dated as of December 30, 2002, between the Company and General Electric Capital Corporation (29)
10.61	Amendment to Promissory Note, dated as of September 27, 2002, by and between the Company and General Electric Capital Corporation (25)
10.62	Promissory Note, dated as of September 26, 2002, by and between the Company and General Electric Capital Corporation (25)
10.63	Employment Agreement, dated March 15, 2006, by and between the Company and Deirdre Y. Gillespie, M.D. (30)*
10.64	Separation Agreement, dated March 17, 2006, by and between the Company and Steven B. Engle (30)*
10.65	Employment Offer Letter, dated July 10, 2006 and executed July 14, 2006, by and between the Company and Michael Tansey, M.D. (34)*
10.66	Employment Agreement, dated December 4, 2006, by and between the Company and Michael Tansey, M.D. (31)*
10.67	Underwriting Agreement, dated as of March 29, 2007, between the Company and Needham & Company, LLC and A.G. Edwards & Sons, Inc. (38)
10.68	Employment Agreement, dated May 10, 2007, by and between the Company and Niv Caviar (36)*
10.69	Promissory Note, dated as of June 28, 2007, between the Company and General Electric Capital Corporation (35)
10.70	Amendment to Chief Executive Officer Employment Agreement (35)*
10.71	Promissory Note, dated as of December 31, 2007, between the Company and General Electric Capital Corporation
10.72	Employment Agreement, dated March 4, 2008, by and between the Company and Luke Seikkula (37)*
21.1	Subsidiaries of La Jolla Pharmaceutical Company (15)
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

<sup>\*</sup> This exhibit is a management contract or compensatory plan or arrangement.

<sup>(1)</sup> Previously filed with the Company's Current Report on Form 8-K filed March 1, 2006 and incorporated by reference herein.

<sup>(2)</sup> Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000 and incorporated by reference herein.

- (3) Previously filed with the Company's Registration Statement on Form S-3 (Registration No. 333-131246) filed January 24, 2006 and incorporated by reference herein.
- (4) Previously filed with the Company's Registration Statement on Form 8-A (Registration No. 000-24274) filed December 4, 1998 and incorporated by reference herein.
- (5) Previously filed with the Company's Current Report on Form 8-K filed January 26, 2001 and incorporated by reference herein. The changes effected by the Amendment are also reflected in the Amendment to Application for Registration on Form 8-A/A filed on January 26, 2001:
- (6) Previously filed with the Company's Current Report on Form 8-K filed December 16, 2005 and incorporated by reference herein.
- (7) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005 and incorporated by reference herein.
- (8) Previously filed with the Company's Registration Statement on Form S-1 (Registration No. 33-76480) filed June 3, 1994 and incorporated by reference herein.
- (9) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994 and incorporated by reference herein.
- (10) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1995 and incorporated by reference herein.
- (11) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 and incorporated by reference herein.
- (12) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996 and incorporated by reference herein.
- (13) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 and incorporated by reference herein.
- (14) Previously filed with the Company's Current Report on Form 8-K filed May 20, 2005 and incorporated by reference herein.
- (15) Previously filed with the Company's Annual Report on Form 10-K for the year ended December 31, 2004 and incorporated by reference herein.
- (16) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997 and incorporated by reference herein.
- (17) Previously filed with the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1999 and incorporated by reference herein.
- (18) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 and incorporated by reference herein.
- (19) Previously filed with the Company's Current Report on Form 8-K filed October 7, 2005 and incorporated by reference herein.
- (20) Previously filed with the Company's Current Report on Form 8-K filed January 28, 2005 and incorporated by reference herein.

- (21) Previously filed with the Company's Current Report on Form 8-K filed February 20, 2004 and incorporated by reference herein.
- (22) Previously filed with the Company's Current Report on Form 8-K filed August 12, 2003 and incorporated by reference herein.
- (23) Previously filed with the Company's Current Report on Form 8-K filed January 16, 2002 and incorporated by reference herein.
- (24) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and incorporated by reference herein.
- (25) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 and incorporated by reference herein.
- (26) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004 and incorporated by reference herein.
- (27) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004 and incorporated by reference herein.
- (28) Previously filed with the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003 and incorporated by reference herein.
- (29) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2003 and incorporated by reference herein.
- (30) Previously filed with the Company's Current Report on Form 8-K filed March 20, 2006 and incorporated by reference herein.
- (31) Previously filed with the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and incorporated by reference herein.
- (32) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006 and incorporated by reference herein.
- (33) Previously filed with the Company's Registration Statement on Form S-8 filed June 12, 2007 and incorporated by reference herein.
- (34) Previously filed with the Company's Current Report on Form 8-K filed July 18, 2006 and incorporated by reference herein.
- (35) Previously filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 and incorporated by reference herein.
- (36) Previously filed with the Company's Current Report on Form 8-K filed May 10, 2007 and incorporated by reference herein.
- (37) Previously filed with the Company's Current Report on Form 8-K filed March 4, 2008 and incorporated by reference herein.
- (38) Previously filed with the Company's Current Report on Form 8-K filed March 30, 2007 and incorporated by reference herein.

# EXECUTIVE OFFICERS AND KEY EMPLOYEES

Deirdre Y. Gillespie, M.D.

President, Chief Executive Officer and Assistant Secretary

#### Niv E. Caviar

Executive Vice President, Chief Business and Financial Officer

# Michael J.B. Tansey, M.D., Ph.D.

Executive Vice President and Chief Medical Officer

#### Josefina T. Elchico

Vice President of Quality Operations

#### Luke Seikkula

Vice President of Manufacturing

### Gail A. Sloan, CPA

Vice President of Finance and Secretary

### Matthew D. Linnik, Ph.D.

Executive Vice President and Chief Scientific Officer

#### Lisa Koch Hulle, RAC, MTOPRA

Vice President of Regulatory Affairs and Project Management

#### Peter D. Potgieter, M.D.

Vice President and Medical Director

#### Vickie Motte

Senior Director of Human Resources

## Andrew Wiseman, Ph.D.

Senior Director of Investor Relations

# **BOARD OF DIRECTORS**

# Craig R. Smith, M.D.

Chairman of the Board President of Williston Consulting LLC

# Deirdre Y. Gillespie, M.D.

President, Chief Executive Officer and Assistant Secretary

#### Thomas H. Adams, Ph.D.

Chief Technology Officer of Iris International, Inc. Founder and Chairman Emeritus of Genta, Inc.

# Robert A. Fildes, Ph.D.

President of SB2, Inc.

# Stephen M. Martin

CEO Partner of Hi Tech Partners, LLC

## Nader J. Naini

General Partner of Frazier Healthcare Ventures

## Martin P. Sutter

Founding Managing Director of Essex Woodlands Health Ventures

# James N. Topper, M.D., Ph.D.

General Partner of Frazier Healthcare Ventures

# Frank E. Young, M.D., Ph.D.

Former Commissioner of the United States Food and Drug Administration Partner of Essex Woodlands Health Ventures CEO of Cosmos Alliance

# **COMPANY ADDRESS**

6455 Nancy Ridge Drive San Diego, California 92121 Phone: 858-452-6600 Facsimile: 858-554-0234

#### TRANSFER AGENT

American Stock Transfer & Trust Company (New York, New York)

#### **INDEPENDENT AUDITORS**

Ernst & Young LLP (San Diego, California)

#### **LEGAL COUNSEL**

Goodwin Procter, LLP (Boston, Massachusetts)

#### **ANNUAL MEETING OF STOCKHOLDERS**

The annual meeting of stockholders will be held at 10:00 a.m. on Thursday, May 22, 2008 at the corporate headquarters of La Jolla Pharmaceutical Company.

# **SEC FILINGS**

A copy of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Exchange Act of 1934 are available without charge by calling our Investor Relations department at (858) 452-6600, by writing to Investor Relations, La Jolla Pharmaceutical Company, 6455 Nancy Ridge Drive, San Diego, California 92121, or by visiting our Web site at www.lipc.com as soon as reasonably practicable after we electronically file or furnish the reports with or to the Securities and Exchange Commission.

#### **COMMON STOCK INFORMATION**

Our common stock trades on the Nasdaq Global Market under the symbol "LJPC."

# FORWARD-LOOKING STATEMENTS

The forward-looking statements in this report involve significant risks, assumptions and uncertainties, and a number of factors, both foreseen and unforeseen, could cause actual results to differ materially from our current expectations. Forward-looking statements include those that express a plan, belief, expectation, estimation, anticipation, intent, contingency, future development or similar expression. The analyses of clinical results of Riquent® (abetimus sodium), previously known as LJP 394, our drug candidate for the treatment of systemic lupus erythematosus (lupus), and any other drug candidate that we may develop, including the results of any trials or models that are ongoing or that we may initiate in the future, could result in a finding that these drug candidates are not effective in large patient populations, do not

provide a meaningful clinical benefit, or may reveal a potential safety issue requiring us to develop new candidates. The analysis of the data from our previous Phase 3 trial of Riquent showed that the trial did not reach statistical significance with respect to its primary endpoint, time to renal flare, or with respect to its secondary endpoint, time to treatment with high-dose corticosteroids or cyclophosphamide. The results from our clinical trials of Riquent, including the results of any trials that are ongoing or that we may initiate in the future, may not ultimately be sufficient to obtain regulatory clearance to market Riquent either in the United States or any other country, and we may be required to conduct additional clinical studies to demonstrate the safety and efficacy of Riquent in order to obtain marketing approval. There can be no assurance, however, that we will have the necessary resources to complete any current or future trials or that any such trials will sufficiently demonstrate the safety and efficacy of Riquent. Our ability to develop and sell our products in the future may be adversely affected by the intellectual property rights of third parties or the validity or enforceability of our intellectual property rights. Additional risk factors include the uncertainty and timing of: our ability to raise additional capital; obtaining required regulatory approvals, including delays associated with any approvals that we may obtain; the timely supply of drug product for clinical trials; our ability to pass all necessary regulatory inspections; the increase in capacity of our manufacturing capabilities for possible commercialization; successfully marketing and selling our products; our lack of manufacturing, marketing and sales experience; our ability to make use of the orphan drug designation for Riquent: generating future revenue from product sales or other sources such as collaborative relationships; future profitability; and our dependence on patents and other proprietary rights. Accordingly, you should not rely upon forward-looking statements as predictions of future events. The outcome of the events described in these forward-looking statements are subject to the risks, uncertainties and other factors described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in the "Risk Factors" contained in this report and in other reports and registration statements that we file with the Securities and Exchange Commission from time to time. We expressly disclaim any intent to update forward-looking statements.

# LA JOLLA PHARMACEUTICAL COMPANY FINANCIAL SNAPSHOT

Stock Listing/Symbol:
Nasdaq: LJPC
Shares Outstanding as of 2/29/08:
39,630,757
Stock Price as of 12/31/07:
\$3.92
Market Cap as of 12/31/07:
\$155.3 million
Cash Position as of 12/31/07:
\$39.4 million
Stock Price Range 2007:

\$2.80-\$8.68

www.ljpc.com

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